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40 CFR Parts 9, 141, and 142
National Primary Drinking Water Regulations: Long Term 2 Enhanced Surface Water Treatment Rule; Final Rule

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Parts 9, 141, and 142

[EPA–HQ–OW–2002–0039; FRL–8013–1]

RIN 2040—AD37

National Primary Drinking Water Regulations: Long Term 2 Enhanced Surface Water Treatment Rule

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: EPA is promulgating National Primary Drinking Water Regulations that require the use of treatment techniques, along with monitoring, reporting, and public notification requirements, for all public water systems that use surface water sources. The purposes of the Long Term 2 Enhanced Surface Water Treatment Rule (LT2ESWTR) are to protect public health from illness due to Cryptosporidium and other microbial pathogens in drinking water and to address risk-risk trade-offs with the control of disinfection byproducts.

Key provisions in the LT2ESWTR include the following: source water monitoring for Cryptosporidium, with a screening procedure to reduce monitoring costs for small systems; risk-targeted Cryptosporidium treatment by filtered systems with the highest source water Cryptosporidium levels; inactivation of Cryptosporidium by all unfiltered systems; criteria for the use of Cryptosporidium treatment and control processes; and covering or treating uncovered finished water storage facilities.

EPA believes that implementation of the LT2ESWTR will significantly reduce levels of infectious Cryptosporidium in finished drinking water. This will substantially lower rates of endemic cryptosporidiosis, the illness caused by Cryptosporidium, which can be severe and sometimes fatal in sensitive subpopulations (e.g., infants, people with weakened immune systems). In addition, the treatment technique requirements of this regulation will increase protection against other microbial pathogens like Giardia lamblia.

DATES: This final rule is effective on March 6, 2006. The incorporation by reference of certain publications listed in the rule is approved by the Director of the Federal Register as of March 6, 2006. For judicial review purposes, this final rule is promulgated as of January 5, 2006.

ADDRESSES: EPA has established a docket for this action under Docket ID No. EPA-HQ-OW–2002–0039. All documents in the docket are listed on the *www.regulations.gov* Web site. Although listed in the index, some information is not publicly available, i.e., CBI or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the Internet and will be publicly available only in hard copy form. Publicly available docket materials are available either electronically through *www.regulations.gov* or in hard copy at the Water Docket, EPA/DC, EPA West, Room B102, 1301 Constitution Ave., NW., Washington, DC. The Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room is (202) 566–1744, and the telephone number for the Water Docket is (202) 566–2426.

FOR FURTHER INFORMATION CONTACT: Daniel C. Schmelling, Standards and Risk Management Division, Office of Ground Water and Drinking Water (MC 4607M), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460; telephone number: (202) 564–5281; fax number: (202) 564–3767; e-mail address: *schmelling.dan@epa.gov*. For general information, contact the Safe Drinking Water Hotline, telephone number: (800) 426–4791. The Safe Drinking Water Hotline is open Monday through Friday, excluding legal holidays, from 9 a.m. to 5 p.m., Eastern time.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Who Is Regulated by This Action?

Entities potentially regulated by the LT2ESWTR are public water systems (PWSs) that use surface water or ground water under the direct influence of surface water (GWUDI). Regulated categories and entities are identified in the following chart.

Category	Examples of regulated entities
Industry	Public Water Systems that use surface water or ground water under the direct influence of surface water.
State, Local, Tribal or Federal Governments	Public Water Systems that use surface water or ground water under the direct influence of surface water.

This table is not intended to be exhaustive, but rather provides a guide for readers regarding entities likely to be regulated by this action. This table lists the types of entities that EPA is now aware could potentially be regulated by this action. Other types of entities not listed in this table could also be regulated. To determine whether your facility is regulated by this action, you should carefully examine the definition of public water system in § 141.3 of Title 40 of the Code of Federal Regulations and applicability criteria in § 141.700(b) of today's rule. If you have questions regarding the applicability of the LT2ESWTR to a particular entity, consult one of the persons listed in the preceding section entitled **FOR FURTHER INFORMATION CONTACT**.

Abbreviations Used in This Document

ASTM American Society for Testing and Materials
AWWA American Water Works Association
°C Degrees Centigrade
CDC Centers for Disease Control and Prevention
CFE Combined Filter Effluent
CFR Code of Federal Regulations
COI Cost-of-Illness
CT The Residual Concentration of Disinfectant (mg/L) Multiplied by the Contact Time (in minutes)
CWS Community Water Systems
DAPI 4′,6-Diamindino-2-phenylindole
DBPs Disinfection Byproducts
DBPR Disinfectants/Disinfection Byproducts Rule
DE Diatomaceous Earth
DIC Differential Interference Contrast (microscopy)
EA Economic Analysis
EPA United States Environmental Protection Agency
GAC Granular Activated Carbon
GWUDI Ground Water Under the Direct Influence of Surface Water
HAA5 Five Haloacetic Acids (Monochloroacetic, Dichloroacetic, Trichloroacetic, Monobromoacetic and Dibromoacetic Acids)
ICR Information Collection Rule (also Information Collection Request)
ICRSS Information Collection Rule Supplemental Surveys

ICRSSM Information Collection Rule Supplemental Survey of Medium Systems
ICRSSL Information Collection Rule Supplemental Survey of Large Systems
IESWTR Interim Enhanced Surface Water Treatment Rule
Log Logarithm (common, base 10)
LRAA Locational Running Annual Average
LRV Log Removal Value
LT1ESWTR Long Term 1 Enhanced Surface Water Treatment Rule
LT2ESWTR Long Term 2 Enhanced Surface Water Treatment Rule
MCL Maximum Contaminant Level
MCLG Maximum Contaminant Level Goal
MG Million Gallons
M–DBP Microbial and Disinfectants/Disinfection Byproducts
MF Microfiltration
NPDWR National Primary Drinking Water Regulation
NTTAA National Technology Transfer and Advancement Act
NTU Nephelometric Turbidity Unit
OMB Office of Management and Budget
PE Performance Evaluation
PWS Public Water System
QC Quality Control
QCRV Quality Control Release Value
RAA Running Annual Average
RFA Regulatory Flexibility Act
RO Reverse Osmosis
SAB Science Advisory Board
SBAR Small Business Advocacy Review
SDWA Safe Drinking Water Act
SWAP Source Water Assessment Program
SWTR Surface Water Treatment Rule
TCR Total Coliform Rule
TTHM Total Trihalomethanes
UF Ultrafiltration
UMRA Unfunded Mandates Reform Act

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II. Summary of the Final Rule

A. Why Is EPA Promulgating the LT2ESWTR?

EPA is promulgating the Long Term 2 Enhanced Surface Water Treatment Rule (LT2ESWTR) to further protect public health against Cryptosporidium and other microbial pathogens in drinking water. Cryptosporidium is a protozoan parasite that is common in surface water used as drinking water sources by public water systems (PWSs). In drinking water, Cryptosporidium is a particular concern because it is highly resistant to chemical disinfectants like chlorine. When ingested, Cryptosporidium can cause acute gastrointestinal illness, which may be severe and sometimes fatal for people with weakened immune systems. Cryptosporidium has been identified as the cause of a number of waterborne disease outbreaks in the United States (details in section III.C).

The LT2ESWTR supplements existing microbial treatment regulations and targets PWSs with higher potential risk from Cryptosporidium. Existing regulations require most PWSs using surface water sources to filter the water, and those PWSs that are required to filter must remove at least 99 percent (2-log) of the Cryptosporidium (details in section III.B). As explained in the proposal for today's rule (68 FR 47640, August 11, 2003) (USEPA 2003a), new data on the occurrence, infectivity, and treatment of Cryptosporidium in drinking water indicate that existing regulations are sufficient for most PWSs. A subset of PWSs with greater vulnerability to Cryptosporidium, however, requires additional treatment.

In particular, recent national survey data show that the level of Cryptosporidium in the sources of most filtered PWSs is lower than previously estimated, but also that Cryptosporidium levels vary widely from source to source. Accordingly, a subset of filtered PWSs has relatively high levels of source water Cryptosporidium contamination. In addition, data from human health studies indicate that the potential for Cryptosporidium to cause infection is likely greater than previously recognized (details in section III.E). These findings have led EPA to conclude that existing requirements do not provide adequate public health protection in filtered PWSs with the highest source water Cryptosporidium levels. Consequently, EPA is establishing risk-targeted additional treatment requirements for such filtered PWSs under the LT2ESWTR.

For PWSs that use surface water sources and are not required to filter (i.e., unfiltered PWSs), existing regulations do not require any treatment for Cryptosporidium. New survey data suggest that typical Cryptosporidium levels in the treated water of unfiltered PWSs are higher than in the treated water of filtered PWSs (USEPA 2003a). Thus, Cryptosporidium treatment by unfiltered PWSs is needed to achieve comparable public health protection (details in section III.E). Further, results from recent treatment studies have allowed EPA to develop standards for the inactivation of Cryptosporidium by ozone, ultraviolet (UV) light, and chlorine dioxide (details in section IV.D). Based on these developments, EPA is establishing requirements under the LT2ESWTR for all unfiltered PWSs to treat for Cryptosporidium, with the required degree of treatment depending on the source water contamination level.

Additionally, the LT2ESWTR addresses risks in uncovered finished water storage facilities, in which treated water can be subject to significant contamination as a result of runoff, bird and animal wastes, human activity, algal growth, insects, fish, and airborne deposition (details in section IV.F). Existing regulations prohibit the building of new uncovered finished water storage facilities but do not deal with existing ones. Under the LT2ESWTR, PWSs must limit potential risks by covering or treating the discharge of such storage facilities.

Most of the requirements in today's final LT2ESWTR reflect consensus recommendations from the Stage 2 Microbial and Disinfection Byproducts (M–DBP) Federal Advisory Committee. These recommendations are set forth in the Stage 2 M–DBP Agreement in Principle (65 FR 83015, December 29, 2000) (USEPA 2000a).

B. What Does the LT2ESWTR Require?

1. Source Water Monitoring

The LT2ESWTR requires PWSs using surface water or ground water under the direct influence (GWUDI) of surface water to monitor their source water (i.e., the influent water entering the treatment plant) to determine an average Cryptosporidium level. As described in the next section, monitoring results determine the extent of Cryptosporidium treatment requirements under the LT2ESWTR.

Large PWSs (serving at least 10,000 people) must monitor for Cryptosporidium (plus E. coli and turbidity in filtered PWSs) for a period of two years. To reduce monitoring costs, small filtered PWSs (serving fewer than 10,000 people) initially monitor just for E. coli for one year as a screening analysis and are required to monitor for Cryptosporidium only if their E. coli levels exceed specified ''trigger'' values. Small filtered PWSs that exceed the E. coli trigger, as well as all small unfiltered PWSs, must monitor for Cryptosporidium for one or two years, depending on the sampling frequency (details sections IV.A).

Under the LT2ESWTR, specific criteria are set for sampling frequency and schedule, sampling location, using previously collected data (i.e., grandfathering), providing treatment instead of monitoring, sampling by PWSs that use surface water for only part of the year, and monitoring of new plants and sources (details in section IV.A). The LT2ESWTR also establishes requirements for reporting of monitoring results (details in section IV.I), using analytical methods (details in section IV.J), and using approved laboratories (details in section IV.K).

The date for PWSs to begin monitoring is staggered by PWS size, with smaller PWSs starting at a later time than larger ones (details in section IV.G). Today's rule also requires a second round of monitoring to begin approximately 6.5 years after the first round concludes in order to determine if source water quality has changed to a degree that should affect treatment requirements (details in section IV.A).

2. Additional Treatment for Cryptosporidium

The LT2ESWTR establishes risk-targeted treatment technique requirements to control Cryptosporidium in PWSs using surface water or GWUDI. These treatment requirements supplement those established by existing regulations, all of which remain in effect under the LT2ESWTR.

Filtered PWSs will be classified in one of four treatment categories (or ''bins'') based on the results of the source water Cryptosporidium monitoring described in the previous section. This bin classification determines the degree of additional Cryptosporidium treatment, if any, the filtered PWS must provide. Occurrence data indicate that the majority of filtered PWSs will be classified in Bin 1, which carries no additional treatment requirements. PWSs classified in Bins 2, 3, or 4 must achieve 1.0- to 2.5-log of treatment (i.e., 90 to 99.7 percent reduction) for Cryptosporidium over and above that provided with conventional treatment. Different additional treatment requirements may apply to PWSs using other than conventional treatment, such as direct filtration, membranes, or cartridge filters (details in section. IV.B). Filtered PWSs must meet the additional Cryptosporidium treatment required in Bins 2, 3, or 4 by using one or more treatment or control processes from a ''microbial toolbox'' of options (details in section. IV.D).

The LT2ESWTR requires all unfiltered PWSs to provide at least 2-log (i.e., 99 percent) inactivation of Cryptosporidium. If the average source water Cryptosporidium level exceeds 0.01 oocysts/L based on the monitoring described in the previous section, the unfiltered PWS must provide at least 3-log (i.e., 99.9 percent) inactivation of Cryptosporidium. Further, under the LT2ESWTR, unfiltered PWSs must achieve their overall inactivation requirements (including Giardia lamblia and virus inactivation as established by earlier regulations) using a minimum of two disinfectants (details in section IV.C).

3. Uncovered Finished Water Storage Facilities

Under the LT2ESWTR, PWSs with uncovered finished water storage facilities must take steps to address contamination risks. Existing regulations require PWSs to cover all new storage facilities for finished water but do not address existing uncovered finished water storage facilities. Under the LT2ESWTR, PWSs using uncovered finished water storage facilities must either cover the storage facility or treat the storage facility discharge to achieve inactivation and/or removal of 4-log virus, 3-log Giardia lamblia, and 2-log Cryptosporidium on a State-approved schedule (details in section. IV.F).

C. Will This Regulation Apply to My Water System?

The LT2ESWTR applies to all PWSs using surface water or GWUDI, including both large and small PWSs, community and non-community PWSs, and non-transient and transient PWSs. Wholesale PWSs must comply with the requirements of today's rule based on the population of the largest PWS in the combined distribution system. Consecutive PWSs that purchase treated water from wholesale PWSs that fully comply with the monitoring and treatment requirements of the LT2ESWTR are not required to take additional steps for that water under today's rule.

III. Background Information

The sections in this part provide summary background information for

today's final LT2ESWTR. Individual sections address the following topics: (A) Statutory requirements and legal authority for the LT2ESWTR; (B) existing regulations for microbial pathogens in drinking water; (C) the problem with Cryptosporidium in drinking water; (D) specific public health concerns addressed by the LT2ESWTR; (E) new information for Cryptosporidium risk management in PWSs; and (F) recommendations from the Stage 2 M-DBP Advisory Committee for the LT2ESWTR. For additional information on these topics, see the proposed LT2ESWTR (USEPA 2003a) and supporting technical material where cited.

A. Statutory Requirements and Legal Authority

The Safe Drinking Water Act (SDWA or the Act), as amended in 1996, requires EPA to publish a maximum contaminant level goal (MCLG) and promulgate a national primary drinking water regulation (NPDWR) with enforceable requirements for any contaminant that the Administrator determines may have an adverse effect on the health of persons, is known to occur or has a substantial likelihood of occurring in public water systems (PWSs) with a frequency and at levels of public health concern, and for which, in the sole judgement of the Administrator, regulation of such contaminant presents a meaningful opportunity for health risk reduction for persons served by PWSs (section 1412 (b)(1)(A)).

MCLGs are non-enforceable health goals and are to be set at a level at which no known or anticipated adverse effects on the health of persons occur and which allows an adequate margin of safety (sections 1412(b)(4) and 1412(a)(3)). EPA established an MCLG of zero for Cryptosporidium under the Interim Enhanced Surface Water Treatment Rule (IESWTR) (63 FR 69478, December 16, 1998) (USEPA 1998a). In today's rule, the Agency is not making any changes to the current MCLG for Cryptosporidium.

The Act also requires each NPDWR for which an MCLG is established to specify a maximum contaminant level (MCL) that is as close to the MCLG as is feasible (sections 1412(b)(4) and 1401(1)(C)). The Agency is authorized to promulgate an NPDWR that requires the use of a treatment technique in lieu of establishing an MCL if the Agency finds that it is not economically or technologically feasible to ascertain the level of the contaminant (sections 1412(b)(7)(A) and 1401(1)(C)). The Act specifies that in such cases, the Agency shall identify those treatment techniques that would prevent known or anticipated adverse effects on the health of persons to the extent feasible (section 1412(b)(7)(A)).

The Agency has concluded that it is not currently economically or technologically feasible for PWSs to determine the level of Cryptosporidium in finished drinking water for the purpose of compliance with a finished water standard. As described in section IV.C, the LT2ESWTR is designed to protect public health by lowering the level of infectious Cryptosporidium in finished drinking water to less than 1 oocyst/10,000 L. Approved Cryptosporidium analytical methods, which are described in section IV.K, are not sufficient to routinely determine the level of Cryptosporidium at this concentration. Consequently, the LT2ESWTR relies on treatment technique requirements to reduce health risks from Cryptosporidium in PWSs.

When proposing an NPDWR that includes an MCL or treatment technique, the Act requires EPA to publish and seek public comment on an analysis of health risk reduction and costs. This includes an analysis of quantifiable and nonquantifiable costs and health risk reduction benefits, incremental costs and benefits of each alternative considered, the effects of the contaminant upon sensitive subpopulations (e.g., infants, children, pregnant women, the elderly, and individuals with a history of serious illness), any increased risk that may occur as the result of compliance, and other relevant factors (section 1412(b)(3)(C)). EPA's analysis of health benefits and costs associated with the LT2ESWTR is presented in the Economic Analysis of the LT2ESWTR (USEPA 2005a) and is summarized in section VI of this preamble. The Act does not, however, authorize the Administrator to use a determination of whether benefits justify costs to establish an MCL or treatment technique requirement for the control of Cryptosporidium (section 1412(b)(6)(C)).

Finally, section 1412(b)(2)(C) of the Act requires EPA to promulgate a Stage 2 Disinfectants and Disinfection Byproducts Rule within 18 months after promulgation of the LT1ESWTR, which occurred on January 14, 2002. Consistent with statutory requirements for risk balancing (section 1412(b)(5)(B)), EPA is finalizing the LT2ESWTR in conjunction with the Stage 2 DBPR to ensure parallel protection from microbial and DBP risks.

B. Existing Regulations for Microbial Pathogens in Drinking Water

This section summarizes existing rules that regulate treatment for pathogenic microorganisms by PWSs using surface water sources. The LT2ESWTR supplements these rules with additional risk-targeted requirements, but does not withdraw any existing requirements.

1. Surface Water Treatment Rule

The Surface Water Treatment Rule (SWTR) (54 FR 27486, June 29, 1989) (USEPA 1989a) applies to all PWSs using surface water or ground water under the direct influence (GWUDI) of surface water as sources (i.e., Subpart H PWSs). It established MCLGs of zero for Giardia lamblia, viruses, and Legionella, and includes the following treatment technique requirements to reduce exposure to pathogenic microorganisms: (1) Filtration, unless specific avoidance criteria are met; (2) maintenance of a disinfectant residual in the distribution system; (3) removal and/or inactivation of 3-log (99.9%) of Giardia lamblia and 4-log (99.99%) of viruses; (4) maximum allowable turbidity in the combined filter effluent (CFE) of 5 nephelometric turbidity units (NTU) and 95th percentile CFE turbidity of 0.5 NTU or less for plants using conventional treatment or direct filtration (with different standards for other filtration technologies); and (5) watershed protection and source water quality requirements for unfiltered PWSs.

2. Total Coliform Rule

The Total Coliform Rule (TCR) (54 FR 27544, June 29, 1989) (USEPA 1989b) applies to all PWSs. It established an MCLG of zero for total and fecal coliform bacteria and an MCL based on the percentage of positive samples collected during a compliance period. Coliforms are used as an indicator of fecal contamination and to determine the integrity of the water treatment process and distribution system. Under the TCR, no more than 5 percent of distribution system samples collected in any month may contain coliform bacteria (no more than 1 sample per month may be coliform positive in those PWSs that collect fewer than 40 samples per month). The number of samples to be collected in a month is based on the number of people served by the PWS.

3. Interim Enhanced Surface Water Treatment Rule

The Interim Enhanced Surface Water Treatment Rule (IESWTR) (63 FR 69478, December 16, 1998) (USEPA 1998a) applies to PWSs serving at least 10,000 people and using surface water or

GWUDI sources. Key provisions established by the IESWTR include the following: (1) An MCLG of zero for Cryptosporidium; (2) Cryptosporidium removal requirements of 2-log (99 percent) for PWSs that filter; (3) more stringent CFE turbidity performance standards of 1.0 NTU as a maximum and 0.3 NTU or less at the 95th percentile monthly for treatment plants using conventional treatment or direct filtration; (4) requirements for individual filter turbidity monitoring; (5) disinfection benchmark provisions to assess the level of microbial protection that PWSs provide as they take steps to comply with new DBP standards; (6) inclusion of Cryptosporidium in the definition of GWUDI and in the watershed control requirements for unfiltered PWSs; (7) requirements for covers on new finished water storage facilities; and (8) sanitary surveys for all surface water systems regardless of size.

The IESWTR was developed in conjunction with the Stage 1 Disinfectants and Disinfection Byproducts Rule (Stage 1 DBPR) (63 FR 69389, December 16, 1998) (USEPA 1998b), which reduced allowable levels of certain DBPs, including trihalomethanes, haloacetic acids, chlorite, and bromate.

4. Long Term 1 Enhanced Surface Water Treatment Rule

The Long Term 1 Enhanced Surface Water Treatment Rule (LT1ESWTR) (67 FR 1812, January 14, 2002) (USEPA 2002a) builds upon the microbial control provisions established by the IESWTR for large PWSs through extending similar requirements to small PWSs. The LT1ESWTR applies to PWSs that use surface water or GWUDI as sources and that serve fewer than 10,000 people. Like the IESWTR, the LT1ESWTR established the following: 2-log (99 percent) Cryptosporidium removal requirements by PWSs that filter; individual filter turbidity monitoring and more stringent combined filter effluent turbidity standards for conventional and direct filtration plants; disinfection profiling and benchmarking; inclusion of Cryptosporidium in the definition of GWUDI and in the watershed control requirements for unfiltered PWSs; and the requirement that new finished water storage facilities be covered.

5. Filter Backwash Recycle Rule

The Filter Backwash Recycling Rule (FBRR) (66 FR 31085, June 8, 2001) (USEPA 2001a) requires PWSs to consider the potential risks associated with recycling contaminants removed during the filtration process. The provisions of the FBRR apply to all PWSs that recycle, regardless of population served. In general, the provisions include the following: (1) PWSs must return certain recycle streams to a point in the treatment process that is prior to primary coagulant addition unless the State specifies an alternative location; (2) direct filtration PWSs recycling to the treatment process must provide detailed recycle treatment information to the State; and (3) certain conventional PWSs that practice direct recycling must perform a one-month, one-time recycling self assessment.

C. Concern With Cryptosporidium in Drinking Water

1. Introduction

EPA is promulgating the LT2ESWTR to reduce the public health risk associated with Cryptosporidium in drinking water. This section describes the general basis for this public health concern through reviewing information in several areas: the nature of Cryptosporidium, health effects, efficacy of water treatment processes, and the incidence of epidemic and endemic disease. Further information about Cryptosporidium is available in the following documents: Cryptosporidium: Human Health Criteria Document (USEPA 2001b), Cryptosporidium: Drinking Water Advisory (USEPA 2001c), and Cryptosporidium: Risks for Infants and Children (USEPA 2001d).

2. What Is Cryptosporidium?

Cryptosporidium is a protozoan parasite that lives and reproduces entirely in one host. Ingestion of Cryptosporidium can cause cryptosporidiosis, a gastrointestinal (GI) illness. Cryptosporidium is excreted in feces. Transmission of cryptosporidiosis occurs through consumption of water or food contaminated with feces or by direct or indirect contact with infected persons or animals (Casemore 1990).

In the environment, Cryptosporidium is present as a thick-walled oocyst containing four organisms (sporozoites); the oocyst wall insulates the sporozoites from harsh environmental conditions. Oocysts are 4–5 microns in length and width. Upon a host's ingestion of oocysts, enzymes and chemicals produced by the host's digestive system cause the oocyst to excyst, or break open. The excysted sporozoites embed themselves in the surfaces of the epithelial cells of the lower small intestine. The organisms then begin absorbing nutrients from their host cells. When these organisms sexually reproduce, they produce thick- and thin-walled oocysts. The host excretes the thick-walled oocysts in its feces; thin-walled oocysts excyst within the host and contribute to further host infection.

The exact mechanism by which Cryptosporidium causes GI illness is not known. Factors may include damage to intestinal structure and cells, changes in the absorption/secretion processes of the intestine, toxins produced by Cryptosporidium or the host, and proteins that allow Cryptosporidium to adhere to host cell surfaces (Carey et al. 2004).

Upon excretion, Cryptosporidium oocysts may survive for months in various environmental media, including soil, river water, seawater, and human and cattle feces at ambient temperatures (Kato et al. 2001, Pokorny et al. 2002, Fayer et al. 1998a and 1998b, and Robertson et al. 1992). Cryptosporidium can also withstand temperatures as low as -20 °C for periods of a few hours (Fayer and Nerad 1996) but are susceptible to desiccation (Robertson et al. 1992).

Cryptosporidium is a widespread contaminant in surface water used as drinking water supplies. For example, among 67 drinking water sources surveyed by LeChevallier and Norton (1995), 87 percent had positive samples for Cryptosporidium. A more recent survey of 80 medium and large PWSs conducted by EPA detected Cryptosporidium in 85 percent of water sources (USEPA 2003a). Cryptosporidium contamination can come from animal agriculture, wastewater treatment plant discharges, slaughterhouses, birds, wild animals, and other sources of fecal matter.

Because different species of Cryptosporidium are very similar in morphology, researchers have focused on genetic differences in trying to classify them. However, discussion on Cryptosporidium taxonomy is complicated by the fact that even within species or strains, there may be differences in infectivity and virulence. Cryptosporidium parvum (C. parvum) has been the primary species of concern to humans. Until recently, some researchers divided C. parvum into two primary strains, genotype 1, which infects humans, and genotype 2, which infects both humans and cattle (Carey et al. 2004). In 2002, Morgan-Ryan et al. proposed that genotype 1 be designated a separate species, C. hominis. Additional Cryptosporidium species infecting other mammals, birds, and reptiles have been documented. In some cases, these species can infect both immunocompromised (having weakened immune systems) and

otherwise healthy humans (Carey et al. 2004).

3. Cryptosporidium Health Effects

Cryptosporidium infection is characterized by mild to severe diarrhea, dehydration, stomach cramps, and/or a slight fever. Incubation is thought to range from 2 to 10 days (Arrowood 1997). Symptoms typically last from several days to 2 weeks, though in a small percentage of cases, the symptoms may persist for months or longer in otherwise healthy individuals.

Symptoms may be more severe in immunocompromised persons (Frisby et al. 1997, Carey et al. 2004). Such persons include those with AIDS, cancer patients undergoing chemotherapy, organ transplant recipients treated with drugs that suppress the immune system, and patients with autoimmune disorders (e.g., Lupus). In AIDS patients, Cryptosporidium has been found in the lungs, ear, stomach, bile duct, and pancreas in addition to the small intestine (Farthing 2000). Immunocompromised patients with severe persistent cryptosporidiosis may die (Carey et al. 2004). Besides the immunocompromised, children and the elderly may be at higher risk from Cryptosporidium than the general population (discussed in section VII.G).

Studies with human volunteers have demonstrated that a low dose of C. parvum (e.g., 10 oocysts) is sufficient to cause infection in healthy adults, although some strains are more infectious than others (DuPont et al. 1995, Chappell et al. 1999, Okhuysen et al. 2002). Studies of immunosuppressed adult mice have demonstrated that a single viable oocyst can induce C. parvum infections (Yang et al. 2000, Okhuysen et al. 2002). The lowest dose tested in any of the human challenge studies was 10 oocysts. Because drinking water exposures are generally projected to be at lower levels (e.g., 1 oocyst), statistical modeling is necessary to project the effects of such exposure. Following the advice of its Science Advisory Board (SAB), EPA has developed a range of models to predict effects of exposure to low doses of Cryptosporidium. These models are discussed in section VI and in the LT2ESWTR Economic Analysis (USEPA 2005a).

The degree and duration of the immune response to Cryptosporidium is not well characterized. In a study by Chappell et al. (1999), volunteers with IgG Cryptosporidium antibodies in their blood were immune to low doses of oocysts. The ID50 (the dose that infects 50 percent of the challenged population) was 1,880 oocysts for those individuals compared to 132 oocysts for individuals that tested negative for those antibodies. However, earlier studies did not observe a correlation between the development of antibodies after Cryptosporidium infection and subsequent protection from illness (Okhuysen et al. 1998).

No cure for cryptosporidiosis is known. Medical care usually involves treatment for dehydration and nutrient loss. Certain antimicrobial drugs like Azithromycin, Paromomycin, and nitazoxanide, the only drug approved for cryptosporidiosis in children, have been partially effective in treating immunocompromised patients (Rossignol et al. 1998). Therapies used to treat retroviruses can be helpful in fighting cryptosporidiosis in people with AIDS and are more effective when used in conjunction with antimicrobial therapy. The effectiveness of antiretroviral therapy is thought to be related to the associated increase in white blood cells rather than the decrease in the amount of virus present.

4. Efficacy of Water Treatment Processes on Cryptosporidium

EPA is particularly concerned about Cryptosporidium because, unlike pathogens such as bacteria and most viruses, Cryptosporidium oocysts are highly resistant to standard disinfectants like chlorine and chloramines (Korich et al. 1990, Ransome et al. 1993, Finch et al. 1997). Consequently, control of Cryptosporidium in most treatment plants is dependent on physical removal processes. However, due to their size (4–5 microns), oocysts can sometimes pass through filters.

Monitoring data on finished water show that Cryptosporidium is sometimes present in filtered, treated drinking water (LeChevallier et al. 1991, Aboytes et al. 2004). For example, Aboytes et al. (2004) analyzed 1,690 finished water samples from 82 plants. Of these, 22 plants had at least one positive sample for infectious Cryptosporidium (1.4 percent of all samples were positive). All positive samples occurred at plants that met existing regulatory standards and many had very low turbidity.

Waterborne outbreaks of cryptosporidiosis have occurred even in areas served by filtered surface water supplies (Solo-Gabriele and Neumeister, 1996). In some cases, outbreaks were attributed to treatment deficiencies, but in others, the treatment provided by the water system met the regulatory requirements in place at that time. These data indicate that even surface water systems that filter and disinfect can still be vulnerable to Cryptosporidium, depending on the source water quality and treatment effectiveness.

Certain alternative disinfectants can be more effective in treating for Cryptosporidium. Both ozone and chlorine dioxide have been shown to inactivate Cryptosporidium, albeit at doses much higher than those required to inactivate Giardia, which has typically been used to set disinfectant doses (summarized in USEPA 2003a). Studies have also demonstrated a synergistic effect of treatment using ozone followed by chlorine or monochloramine (Rennecker et al. 2000, Driedger et al. 2001). Significantly, UV light has recently been shown to achieve high levels of Cryptosporidium inactivation at feasible doses (summarized in USEPA 2003a).

Other processes that can help reduce Cryptosporidium levels in finished water include watershed management programs, pretreatment processes like bank filtration, and additional clarification and filtration processes during water treatment. Further, optimizing treatment performance and achieving very low levels of turbidity in the finished water has been shown to improve Cryptosporidium removal in treatment plants (summarized in USEPA 2003a).

5. Epidemic and Endemic Disease From Cryptosporidium

Cryptosporidium has caused a number of waterborne disease outbreaks since 1984 when the first was reported in the United States. Data from the Centers for Disease Control and Prevention (CDC) include ten outbreaks caused by Cryptosporidium in drinking water between 1984 and 2000, with approximately 421,000 cases of illness (CDC 1993, 1996, 1998, 2000, and 2002). The most serious outbreak occurred in 1993 in Milwaukee; an estimated 403,000 people became sick (MacKenzie et al. 1994), and at least 50 Cryptosporidium-associated deaths occurred among the severely immunocompromised (Hoxie et al. 1997). Further, a study by McDonald et al. (2001) using blood samples from Milwaukee children suggests that Cryptosporidium infection was more widespread than might be inferred from the illness estimates by MacKenzie et al. (1994).

The number of identified and reported outbreaks in the CDC database is believed to substantially understate the actual incidence of waterborne disease outbreaks and cases (Craun and Calderon 1996, National Research Council 1997). This under reporting is

due to a number of factors. Many people experiencing gastrointestinal illness do not seek medical attention. Where medical attention is provided, the pathogenic agent may not be identified through routine testing. Physicians and patients often lack sufficient information to attribute gastrointestinal illness to any specific origin, such as drinking water, and few States have an active outbreak surveillance program. In addition, if drinking water is investigated as the source of an outbreak, oocysts may not be detected in water samples even if they are present, due to limitations in analytical methods. Consequently, outbreaks may not be recognized in a community or, if recognized, may not be traced to a drinking water source.

In addition, an unknown but probably significant portion of waterborne disease is endemic (i.e., isolated cases not associated with an outbreak) and, thus, is even more difficult to recognize. In an outbreak, if the pathogen has been identified, medical providers and public health investigators know what to look for. In endemic disease, there is no investigation, so the illness may never be identified, or if it is, it may not be linked to a source (e.g., drinking water, person-to-person transmission). In addition, where a pathogen is identified, lab results may not be reported to public health agencies.

Because of this under reporting, the actual incidence of cryptosporidiosis associated with drinking water is unknown. However, indications of this incidence rate can be roughly extrapolated from different sources. Mead et al. (1999) estimated approximately 300,000 total cases of cryptosporidiosis annually that result in a physician visit, with 90 percent of these attributed to waterborne (drinking water and recreational water) and secondary transmission. This estimate is based on the percentage of stools that test positive for Cryptosporidium and applying this percentage to the approximately 15 million physician visits for diarrhea each year. While the fraction of cryptosporidiosis cases that result in a physician visit is unknown, Corso et al. (2003) reported that during the 1993 outbreak in Milwaukee, medical care was sought in approximately 12 percent of all cryptosporidiosis cases.

Surveillance data from the CDC for 2001 show an overall incidence of 1.5 laboratory diagnosed cases of cryptosporidiosis per 100,000 population (CDC, 2002). Although the fraction of all cryptosporidiosis cases that are laboratory confirmed is unknown, during the 1993 Milwaukee outbreak, 739 cases from an estimated 403,000 cases total were confirmed by a laboratory (MacKenzie et al., 1994). These data indicate a ratio of 1 laboratory confirmed case per 545 people estimated to be ill with cryptosporidiosis.

A few studies have attempted to determine exposure in certain areas by measuring seroprevalence of Cryptosporidium antibodies (the frequency at which antibodies are found in the blood). Detection of such antibodies (seropositivity), however, does not mean that the person actually experienced symptoms of cryptosporidiosis. An individual can be asymptomatically infected and still excrete oocysts. Seroprevalence, though, is still a method for estimating the exposure to Cryptosporidium that has occurred within a limited time period (the antibodies may last only a few months).

Frost et al. (2001) conducted a paired city study, in which the serological response of blood donors in a city using ground water as its water source was compared to that of donors in a city using surface water as its source. Rates of seropositivity were higher (49 vs. 36 percent) in the city with the surface water source. A similar study in two other cities (Frost et al. 2002) showed a seropositivity rate of 54 percent in the city served by surface water compared to 38 percent in the city served by ground water. These studies suggest that drinking water from surface sources may be a factor in the higher rates of seropositivity.

D. Specific Concerns Following the IESWTR and LT1ESWTR

In the LT2ESWTR, EPA is addressing a number of public health concerns that remain following implementation of the IESWTR and LT1ESWTR. These are as follows:

- The need for filtered PWSs with higher levels of source water Cryptosporidium contamination to provide additional risk-based treatment for Cryptosporidium beyond IESWTR or LT1ESWTR requirements;
- The need for unfiltered PWSs to provide risk-based treatment for Cryptosporidium to achieve equivalent public health protection with filtered PWSs; and
- The need for PWSs with uncovered finished water storage facilities to take steps to reduce the risk of contamination of treated water prior to distribution to consumers.

EPA and stakeholders identified each of these issues as public health concerns during development of the IESWTR (USEPA 1994, 1997). However, the Agency was unable to address these concerns in those regulations due to data gaps in the areas of health effects, occurrence, analytical methods, and treatment. Consequently, EPA followed a two-stage strategy for microbial and disinfection byproducts rules. Under this strategy, the IESWTR and LT1ESWTR were promulgated to provide an initial improvement in public health protection in large and small PWSs, respectively, while additional data to support a more comprehensive regulatory approach were collected.

Since promulgating the IESWTR and LT1ESWTR, EPA has worked with stakeholders to collect and analyze significant new information to fill data gaps related to Cryptosporidium risk management in PWSs. The next section presents EPA's evaluation of these data and their implications for both the risk of Cryptosporidium in filtered and unfiltered PWSs and the feasibility of steps to limit this risk. In addition, the Agency has evaluated additional data related to mitigating risks with uncovered finished water storage facilities, which are presented in section IV.F.

E. New Information on Cryptosporidium Risk Management

EPA and stakeholders determined during development of the IESWTR that in order to establish risk-based treatment requirements for Cryptosporidium, additional information was needed in the following areas: (1) The risk associated with a given level of Cryptosporidium (i.e., infectivity); (2) the occurrence of Cryptosporidium in PWS sources; (3) analytical methods that would suffice for making site-specific source water Cryptosporidium density estimates; and (4) the use of treatment technologies to achieve specific levels of Cryptosporidium disinfection (USEPA 1997).

In today's final LT2ESWTR, EPA is promulgating risk-based Cryptosporidium treatment requirements for filtered and unfiltered PWSs. The Agency believes that the critical data gaps in the areas of infectivity, occurrence, analytical methods, and treatment that prevented the adoption of such an approach under earlier regulations have been addressed. The new information that the Agency and stakeholders evaluated in each of these areas and its significance for today's LT2ESWTR are summarized as follows. See section VI.L for a summary of public comments on EPA's use of Cryptosporidium infectivity and

occurrence data in assessing benefits of the LT2ESWTR.

1. Infectivity

Infectivity relates the probability of infection to the number of Cryptosporidium oocysts that a person ingests. It is used to predict the disease burden associated with a particular Cryptosporidium level in drinking water. Information on Cryptosporidium infectivity comes from dose-response studies where healthy human volunteers ingest different numbers of oocysts (i.e., the ''dose'') and are subsequently evaluated for signs of infection and illness (i.e., the ''response'').

Prior to the IESWTR, data from a human dose-response study of one Cryptosporidium isolate (IOWA) had been published (DuPont et al. 1995). Following IESWTR promulgation, a study of two additional isolates (TAMU and UCP) was completed and published (Okhuysen et al. 1999). This 1999 study also reanalyzed the IOWA study results. The measured infectivity of Cryptosporidium oocysts varied over a wide range in the Okhuysen et al. (1999) study. The UCP oocysts were much less infective than the IOWA oocysts, and the TAMU oocysts were much more infective.

EPA analyzed these new data for the proposed LT2ESWTR using two different dose-response models. This analysis suggested that the overall infectivity of Cryptosporidium is greater than was estimated for the IESWTR (USEPA 2003a). Specifically, EPA estimated the mean probability of infection from ingesting a single infectious oocyst ranges from 7 to 10 percent. This infection rate is approximately 20 times higher than the estimate of 0.4 percent used in the IESWTR.

Since the publication of the proposed LT2ESWTR, EPA has evaluated three additional studies of Cryptosporidium infectivity. EPA also received a recommendation from the SAB that it analyze Cryptosporidium infectivity data using a wider range of models. Accordingly, EPA re-estimated Cryptosporidium infectivity using the new data and six different dose-response models, including the two models used at proposal. Estimates from the new data and models for the probability of infection from ingesting a single infectious oocyst range from 4 to 16 percent. A detailed discussion of the models and their varying assumptions is provided in the LT2ESWTR Economic Analysis (USEPA 2005a).

As is apparent from these results, substantial uncertainty about the infectivity of Cryptosporidium remains in several areas. These include the variability in host susceptibility, response at very low oocyst doses typical of drinking water ingestion, and the relative infectivity and occurrence of different Cryptosporidium isolates in the environment. To address this uncertainty, EPA conducted its health risk reduction and benefits analyses using a representative range of model results. In the summary tables for these analyses, three sets of estimates are presented: A ''high'' estimate based on the model that showed the highest mean baseline risk; a ''medium'' estimate, based on the models and data used at proposal, which also happens to be in the middle of the range of estimates produced by the six models using the newly available data; and a ''low'' estimate, based on the model that showed the lowest mean baseline risk.

These estimates should not be construed as upper and lower bounds on illnesses avoided and benefits. For each model, a distribution of effects is estimated, and the ''high'' and ''low'' estimates show only the means of these distributions for two different model choices. The detailed distribution of effects is presented for the proposal model in the Economic Analysis (USEPA 2005a). Further, the six dose-response models used in this analysis do not cover all possible variations of models that might have been used with the data, and it is possible that estimates with other models would fall outside the range presented. However, as discussed in the Economic Analysis, EPA believes that the models used in the analyses reflect a reasonable range of results based on important dimensions of model choice.

Regardless of which model is chosen, the available infectivity data suggest that the risk associated with a given concentration of Cryptosporidium is most likely higher than EPA had estimated for the IESWTR. This finding supports the need for increased treatment for Cryptosporidium as required under the LT2ESWTR.

2. Occurrence

Information on the occurrence of Cryptosporidium oocysts in drinking water sources is a critical parameter for assessing risk and the need for additional treatment for this pathogen. For the IESWTR, EPA had no national survey data on Cryptosporidium occurrence and relied instead on several studies that were local or regional. After promulgating the IESWTR, EPA obtained data from two national surveys, the Information Collection Rule (ICR) and the ICR Supplemental Surveys (ICRSS), which were designed to provide improved estimates of occurrence on a national basis.

The ICR included monthly sampling for Cryptosporidium and other water quality parameters from the sources of approximately 350 large PWSs over 18 months. The ICRSS involved twice-per-month Cryptosporidium sampling from the sources of a statistically random sample of 40 large and 40 medium PWSs over 12 months. In addition, the ICRSS required the use of an improved analytical method for Cryptosporidium analysis that had a higher method recovery (the likelihood that an oocyst present in the sample will be counted) and enhanced sample preparation procedures.

EPA analyzed ICR and ICRSS data using a statistical model to account for factors like method recovery and sample volume analyzed. As described in more detail in EPA's Occurrence and Exposure Assessment for the LT2ESWTR (USEPA 2005b), the ICR and ICRSS results demonstrate two main differences for filtered PWSs in comparison to Cryptosporidium occurrence data used for the IESWTR:

(1) The occurrence of Cryptosporidium in many drinking water sources is lower than was indicated by the data used in IESWTR. For example, median Cryptosporidium levels for the ICR and ICRSS data are approximately 0.05/L, which is nearly 50 times lower than the median IESWTR estimates of 2.3 oocysts/L (USEPA 1998a).

(2) Cryptosporidium occurrence is more variable from location to location than was shown by the data considered for the IESWTR. This finding demonstrates that, although median occurrence levels are below those estimated for the IESWTR, a subset of PWSs contains Cryptosporidium levels that are considerably greater than the median.

These results, therefore, indicate that Cryptosporidium levels are relatively low in most water sources, but a subset of sources with relatively higher concentrations may require additional treatment. These findings support a risk-targeted approach for the LT2ESWTR wherein additional Cryptosporidium treatment is required only for filtered PWSs with the highest source water pathogen levels.

Only the ICR provided data to evaluate Cryptosporidium occurrence in unfiltered PWS sources. The median Cryptosporidium level among unfiltered PWS sources was 0.0079 oocysts/L. This level is approximately 10 times lower than the median level for filtered PWS sources.

When the Cryptosporidium removal that filtered PWSs achieve is taken into account, these occurrence data suggest that unfiltered PWSs typically have

higher concentrations of Cryptosporidium in their treated water than filtered PWSs. EPA has estimated that on average, conventional filtration plants remove around 99.9 percent (3-log) of the Cryptosporidium present in the source water. Most unfiltered PWSs, however, provide no treatment for Cryptosporidium. If an unfiltered PWS had a source water Cryptosporidium level 10 times lower than a filtered PWS and the filtered PWS achieved 3-log Cryptosporidium removal, then the Cryptosporidium level in the treated water of the unfiltered PWS would be 100 times higher than in the filtered PWS.

These results suggest that to achieve public health protection equivalent to that provided by filtered PWSs, unfiltered PWSs must take additional steps. Thus, this finding supports the need for Cryptosporidium treatment requirements for unfiltered PWSs under the LT2ESWTR.

3. Analytical Methods

To establish risk-targeted treatment requirements, analytical methods must be available to estimate the contaminant densities in PWS sources. These density estimates are used to determine the level of treatment that is needed at a particular site.

When EPA developed the IESWTR, the best available method for measuring Cryptosporidium was the Information Collection Rule Protozoan Method (ICR Method). The ICR Method provided a quantitative measurement of Cryptosporidium oocysts, but typically undercounted the actual occurrence due to low method recovery. For example, in a spiking study (studies in which known quantities of oocysts are added to water samples) conducted during the ICR survey, the mean recovery of spiked Cryptosporidium oocysts was only 12 percent (Scheller et al. 2002). EPA concluded that the ICR Method was adequate for making national occurrence estimates in the ICR survey but would not suffice for making estimates of Cryptosporidium levels at specific sites.

Subsequent to promulgating the IESWTR, EPA developed an improved Cryptosporidium method, EPA Method 1622 (and later, 1623), to achieve higher recovery rates and lower inter- and intra-laboratory variability than previous methods. Methods 1622 and 1623 incorporate improvements in the concentration, separation, staining, and microscope examination procedures. During the ICRSS, which required the use of Method 1622 or 1623, a spiking study demonstrated a mean Cryptosporidium recovery of 43 percent (Connell et al. 2000). Thus, mean Cryptosporidium recovery with Methods 1622 and 1623 was more than 3.5 times higher compared to the ICR Method performance in the earlier spiking study. In addition, the relative variation in recovery from sample to sample was lower with Methods 1622 and 1623.

As described in section IV of this preamble, EPA has concluded that a monitoring program using Methods 1622 or 1623 can be effective in characterizing PWSs source water Cryptosporidium levels for purposes of determining the need for additional treatment requirements. This finding supports the feasibility of risk-targeted treatment requirements under the LT2ESWTR.

4. Treatment

To establish risk-targeted Cryptosporidium treatment requirements, feasible treatment processes must be available that allow PWSs to inactivate or remove Cryptosporidium. PWSs may then implement these treatment processes to comply with additional treatment requirements.

During development of the IESWTR, EPA recognized that chlorine, the most commonly used disinfectant, is ineffective for inactivating Cryptosporidium. Studies suggested that other disinfectants like ozone and chlorine dioxide could be effective against Cryptosporidium. However, EPA concluded that data available at that time were not sufficient to define how any disinfectant could be applied to achieve a specific level of Cryptosporidium inactivation (USEPA 1997). This conclusion was due in part to methodological inconsistencies and shortcomings in the available studies.

With the completion of major studies since promulgation of the IESWTR, EPA has acquired the data necessary to establish standards for Cryptosporidium inactivation by several disinfectants. For ozone and chlorine dioxide, EPA reviewed new studies by Rennecker et al. (1999), Owens et al. (1999, 2000), Oppenheimer et al. (2000), Ruffell et al. (2000), and Li et al. (2001). Collectively, these studies cover a wide range of both natural and laboratory water conditions. Based on these studies, EPA has developed tables that specify the product of ozone or chlorine dioxide concentration and time of exposure (i.e., CT tables) needed to achieve up to 3-log Cryptosporidium inactivation. Section IV.D of this preamble shows these tables.

Most significantly, many recent studies have demonstrated that UV light is efficient for inactivating high levels of Cryptosporidium. These studies include Clancy et al. (1998, 2000, 2002), Bukhari et al. (1999), Craik et al. (2000, 2001), Landis et al. 2000), Sommer et al. (2001), Shin et al. (2001), and Oppenheimer et al. (2002). Using results from these studies, EPA has defined the UV light intensity and exposure time required for up to 4-log Cryptosporidium inactivation. Section IV.D presents these values. EPA has determined that UV light is a feasible technology for PWSs of all sizes to inactivate Cryptosporidium.

EPA has also developed standards for processes that physically remove Cryptosporidium contamination. These processes include river bank filtration, sedimentation basins, bag filters, cartridge filters, and membranes. Section IV.D presents design and operational standards for these processes, along with a summary of supporting studies.

The development of these standards for Cryptosporidium inactivation and removal processes overcomes a significant limitation that existed when EPA developed the IESWTR. These standards will allow PWSs to implement cost-effective strategies to comply with additional Cryptosporidium treatment requirements under the LT2ESWTR.

F. Federal Advisory Committee Recommendations

EPA convened the Stage 2 M–DBP Federal Advisory Committee in March 1999 to evaluate new information and develop recommendations for the LT2ESWTR and Stage 2 DBPR. The Committee was comprised of representatives from EPA, State and local public health and regulatory agencies, local elected officials, Indian Tribes, drinking water suppliers, chemical and equipment manufacturers, and public interest groups. A technical workgroup provided analytical support for the Committee's discussions.

Committee members signed an Agreement in Principle in September 2000 stating consensus recommendations of the group. The Agreement was published in a December 29, 2000 **Federal Register** notice (USEPA 2000a). For the LT2ESWTR, the consensus recommendations of the Committee are summarized as follows:

(1) Supplemental risk-targeted Cryptosporidium treatment by filtered PWSs with higher source water contaminant levels as shown by monitoring results;

(2) Cryptosporidium inactivation by all unfiltered PWSs, which must meet

overall treatment requirements using a minimum of 2 disinfectants;

(3) A ''toolbox'' of treatment and control processes for PWSs to comply with Cryptosporidium treatment requirements;

(4) Reduced monitoring burden for small filtered PWSs;

(5) Future monitoring to confirm or revise source water quality assessments;

(6) Development of guidance for UV disinfection and other toolbox components; and

(7) Cover or treat existing uncovered finished water reservoirs (i.e., storage facilities) or implement risk mitigation plans.

These recommendations reflect a Committee judgement that, based on available information, additional risk-based Cryptosporidium treatment requirements for filtered and unfiltered PWSs are appropriate and feasible under the LT2ESWTR. Much of today's final LT2ESWTR reflects the Committee's recommendations. The next part of this preamble describes specific requirements of the rule.

IV. Explanation of Today's Action

A. Source Water Monitoring Requirements

Today's rule requires PWSs using surface water or GWUDI sources to monitor their source water to assess the level of Cryptosporidium. Monitoring results assign a PWS to a Cryptosporidium treatment bin, which determines the extent of additional Cryptosporidium treatment requirements (sections IV.B and IV.C described treatment requirements for filtered and unfiltered PWSs, respectively).

Source water monitoring under the LT2ESWTR is designed to ascertain the mean level of Cryptosporidium in the influent to a surface water treatment plant. Requirements differ by PWS size (above or below 10,000 people served) and treatment plant type (filtered or unfiltered PWS). This section describes monitoring requirements for sampling parameters and frequency, sampling location, sampling schedule, monitoring plants that operate only part of the year, failing to monitor, providing treatment instead of monitoring, grandfathering previously collected data, ongoing watershed assessment, second round of monitoring, and new source monitoring.

Other sections of this preamble describe additional requirements related to monitoring, including compliance schedules (section IV.G), reporting of monitoring results (section IV.I), use of approved analytical methods, including minimum sample volume (section IV.J), and use of approved laboratories (section IV.K). As described in section IV.G, monitoring compliance dates under the LT2ESWTR are staggered: smaller PWSs begin monitoring after larger PWSs.

For additional information, see Source Water Monitoring Guidance Manual for Public Water Systems under the Long Term 2 Enhanced Surface Water Treatment Rule. This document provides guidance on sampling location, procedures for collecting and shipping samples, contracting with laboratories, and related topics to assist PWSs in complying with LT2ESWTR monitoring requirements. It may be acquired from EPA's Safe Drinking Water Hotline, which can be contacted as described under **FOR FURTHER INFORMATION CONTACT** at the beginning of this document.

1. Today's Rule

a. *Sampling parameters and frequency.* Requirements for the source water parameters that PWSs must measure under the LT2ESWTR, as well as the sampling frequency and duration, are stated as follows for large and small PWSs, including both filtered and unfiltered plants:

Large Filtered PWSs

Filtered PWSs serving at least 10,000 people must sample at least monthly for Cryptosporidium, E. coli, and turbidity for a period of two years. Sampling may be conducted at a higher frequency (e.g., twice-per-month, once-per-week) but the sampling must be evenly spaced throughout the monitoring period. As described in section IV.B, filtered PWSs that sample at least twice-per-month over two years use a different calculation, which is less conservative, to determine their treatment bin classification under the LT2ESWTR.

Large Unfiltered PWSs

Unfiltered PWSs serving at least 10,000 people must also sample for Cryptosporidium at least monthly for a period of 2 years. No E. coli or turbidity monitoring is required for unfiltered PWSs. Unfiltered PWSs may choose to sample more frequently; however, as described in section IV.C, a higher sampling frequency does not change the calculation used to determine unfiltered PWS Cryptosporidium treatment requirements.

Small Filtered PWSs

Filtered PWSs serving fewer than 10,000 people (i.e., small PWSs) monitor under the LT2ESWTR using a two-phase strategy that begins with an indicator screening analysis. Small filtered PWSs must initially sample for E. coli at least once every two weeks for a period of one year. Cryptosporidium monitoring is required of these PWSs only if the indicator monitoring results meet one of the following conditions:

(1) For PWSs using lake/reservoir sources, the annual mean E. coli concentration is greater than 10 E. coli/100 mL.

(2) For PWSs using flowing stream sources, the annual mean E. coli concentration is greater than 50 E. coli/100 mL.

PWSs using ground water under the direct influence of surface water must comply with the requirement to monitor for Cryptosporidium based on the E. coli level that applies to the nearest surface water body. If no surface water body is nearby, the PWS must comply based on the requirements that apply to PWSs using lake/reservoir sources.

The State may approve small filtered PWSs to monitor for an indicator other than E. coli. The State also may approve an alternative E. coli concentration to trigger Cryptosporidium monitoring. This approval must be in writing and must be based on a State determination that the alternative indicator and/or trigger level will more accurately identify whether a PWS will exceed the Bin 1 Cryptosporidium level of 0.075 oocysts/L, as stated in section IV.B.1 of this preamble. EPA will issue guidance to States on alternative indicators and trigger levels, if warranted, based on large PWS monitoring results.

Small filtered PWSs may elect to skip E. coli monitoring if they notify the State that they will monitor for Cryptosporidium. PWSs must notify the State no later than three months prior to the date the PWS is required to begin monitoring (see section IV.G for specific dates).

Small filtered PWSs that are required to monitor for Cryptosporidium must conduct this monitoring using either of two frequencies: (1) Sample at least twice-per-month for a period of one year or (2) sample at least once-per-month for a period of two years. Note that the same treatment compliance dates apply to the PWS regardless of which Cryptosporidium sampling frequency is used (i.e., selecting the two-year Cryptosporidium sampling frequency does not extend Cryptosporidium treatment compliance deadlines).

Small Unfiltered PWSs

All unfiltered PWSs serving fewer than 10,000 people must monitor for Cryptosporidium. The E. coli screening analysis used by small filtered PWSs is not applicable to small unfiltered PWSs. Small unfiltered PWSs must use either

of the same two Cryptosporidium sampling frequencies available to small filtered PWSs: (1) Sample twice-per-month for one year or (2) sample once-per-month for two years. As with small filtered PWSs, the same treatment compliance dates apply to the PWS regardless of which Cryptosporidium sampling frequency is used.

b. *Sampling location.* PWSs must collect source water samples for each plant that treats a surface water or GWUDI source. However, where multiple plants receive all of their water from the same influent, such as plants that draw water from the same intake or pipe, the State may approve one set of monitoring results to be applied to all plants.

PWSs must collect source water samples prior to chemical treatment, such as coagulants, oxidants, and disinfectants, unless the following condition is met: The State may approve a system to collect a sample after chemical treatment if the State determines that collecting a sample prior to chemical treatment is not feasible and that the chemical treatment is unlikely to have a significant adverse effect on the analysis of the sample. PWSs that recycle filter backwash must collect samples prior to the point of filter backwash addition due to the likely presence of coagulant and other treatment chemicals in the backwash. See section IV.D.6 for directions on sampling location for PWSs using bank filtration.

For plants that use multiple water sources at the same time, PWSs must collect samples from a tap where the sources are combined prior to treatment, if available. If a blended source tap is not available, PWSs must collect samples from each source and either analyze a weighted composite (blended) sample or analyze samples from each source separately and determine a weighted average of the results. The weighting of sources must reflect the relative usage of the different sources by the treatment plant at the time the sample is collected.

PWSs must submit a description of their proposed sampling location(s) to the State no later than three months prior to the date the PWS must begin monitoring (see section IV.G for specific dates). This description must address the position of the sampling location in relation to the PWS's water source(s) and treatment processes, including points of chemical addition and filter backwash recycle. If the State does not respond to a PWS regarding sampling location(s), the PWS must begin sampling at the reported location. See Source Water Monitoring Guidance Manual for Public Water Systems under the Long Term 2 Enhanced Surface Water Treatment Rule, which can be acquired as stated previously, for guidance on sampling location descriptions.

c. *Sampling schedule.* PWSs must collect samples in accordance with a schedule that the PWS develops and reports prior to initiating monitoring. The sampling schedule must specify the calendar dates when the PWS will collect each required sample in a particular round of monitoring. Scheduled sampling dates must be evenly distributed throughout the monitoring period, but may be arranged to accommodate holidays, weekends, and other events when collecting or analyzing a sample would be problematic (e.g., a PWS is not required to schedule samples on the same calendar date each month).

PWSs must submit sampling schedules no later than three months prior to the date the PWS must begin a round of monitoring (see section IV.G for specific dates). Unless the State approves an alternative procedure, large PWSs (serving at least 10,000 people) must report their sampling schedule for initial source water monitoring to EPA using the LT2ESWTR electronic data reporting and review system described in section IV.I. Schedules for initial monitoring by small PWSs and for the second round of monitoring by all PWSs must be reported to the State. PWSs should verify that their laboratory can accommodate the scheduled sampling dates before submitting the schedule.

EPA will not formally approve sampling schedules but will notify a PWS if its sampling schedules does not meet the requirements of today's rule (e.g., does not include the required number of samples). If a PWS does not receive notification from the State or EPA regarding the sampling schedule, the PWS must begin monitoring according to the reported sampling schedule.

PWSs must collect samples within two days before or two days after the dates indicated in their sampling schedules (i.e., within a 5-day period around the schedule date) unless one of the following two conditions applies:

(1) If an extreme condition or situation exists that may pose danger to the sample collector, or that cannot be avoided and causes the PWS to be unable to sample in the scheduled 5-day period, the PWS must sample as close to the scheduled date as is feasible unless the State approves an alternative sampling date. The PWS must submit an explanation for the delayed sampling date to the State concurrent with the shipment of the samples to the laboratory.

(2) If a PWS is unable to report a valid analytical result for a scheduled sampling date due to equipment failure, loss of or damage to the sample, failure to comply with the analytical method requirements, or the failure of an approved laboratory to analyze the sample, then the PWS must collect a replacement sample. Collection of the replacement sample must occur within 21 days of the PWS receiving information that an analytical result cannot be reported for the scheduled date unless the PWS demonstrates that collecting a replacement sample within this time frame is not feasible or the State approves an alternative resampling date. The PWS must submit an explanation for the resampling date to the State concurrent with the shipment of the sample to the laboratory.

Failure to collect a required sample within the 5-day period around a scheduled date that does not meet one of these two conditions is a monitoring violation. PWSs must revise their sampling schedules to add dates for collecting all missed samples and must submit the revised schedule to the State for approval prior to when the PWS begins collecting the missed samples.

d. *Plants operating only part of the year.* Some PWSs operate surface water treatment plants for only part of the year. This includes PWSs that provide water for only a fraction of the year (e.g., resorts open only in the summer) and PWSs that use a surface water plant to supplement another source only during periods of high demand.

Most LT2ESWTR monitoring, treatment, and implementation schedule requirements apply to such plants. Monitoring requirements, however, differ in two respects:

(1) PWSs must conduct sampling only during months of the 2 year monitoring period when the plant operates unless the State specifies another monitoring period based on plant operating practices; and

(2) For plants that operate less than six months per year and where Cryptosporidium monitoring is required, PWSs must collect at least six Cryptosporidium samples per year during each of two years of monitoring.

e. *Failing to monitor.* Today's rule requires PWSs to provide a Tier 3 public notice for violation of monitoring and testing procedure requirements, including the failure to collect one or two source water Cryptosporidium samples. If a PWS fails to collect three or more Cryptosporidium samples, other than in specifically exempted situations (see section IV.A.1.c), the PWS must

provide a Tier 2 special public notice. Violations for failing to monitor persist until the State determines that the PWS has begun sampling on a revised schedule that includes dates for the collection of missed samples. Section IV.H provides further details on public notice requirements of the LT2ESWTR.

PWSs must report their bin classification (or mean Cryptosporidium level for unfiltered PWSs) no later than six months after the end of the scheduled monitoring period (specific dates in section IV.G). Failure by a PWS to collect the required number of Cryptosporidium samples to report its bin classification or mean Cryptosporidium level by the compliance date is a treatment technique violation and the PWS must provide a Tier 2 special public notice (unless the PWS has already provided a Tier 2 public notice for missing three sampling dates and is successfully meeting a State-approved schedule for sampling). The treatment technique violation and public notice requirements persist until the State determines that the PWS is implementing a State-approved monitoring plan to allow bin classification or will install the highest level of treatment required under the rule, as described next.

f. *Providing treatment instead of monitoring.* PWSs are not required to conduct source water monitoring under the LT2ESWTR for plants that will provide the highest level of treatment required under the rule. This applies both to plants that provide this level of treatment at the time the plant would otherwise begin source water monitoring and to plants that commit to install technology to achieve this level of treatment by the applicable compliance date for meeting Cryptosporidium treatment requirements under the LT2ESWTR.

Filtered PWSs are not required to monitor at plants that will provide a total of at least 5.5-log of treatment for Cryptosporidium, equivalent to meeting the treatment requirements of Bin 4 as discussed in section IV.B. Unfiltered PWSs are not required to monitor for plants that will provide a total of at least 3-log of Cryptosporidium inactivation, equivalent to meeting the treatment requirements for unfiltered PWSs with source water Cryptosporidium levels above 0.01 oocysts/L as discussed in section IV.C.

PWSs that intend to provide this level of treatment rather than initiate monitoring must notify the State no later than three months prior to the month the PWS must otherwise begin monitoring. PWSs submit this notification in lieu of submitting a sampling schedule. In addition, a PWS may choose to stop sampling at any point after it has initiated monitoring if it notifies the State that it will provide the highest level of treatment. In both cases, the PWSs must install and operate technologies to achieve this level of treatment no later than the applicable Cryptosporidium treatment compliance date for the PWS as specified in section IV.G. Failure to provide this treatment by the compliance date is a treatment technique violation.

g. *Grandfathering previously collected data.* If the State approves, PWSs may comply with the initial source water monitoring requirements of today's rule by using (i.e., grandfathering) sample results collected before the PWS is required to begin monitoring. PWSs may grandfather monitoring results either in lieu of or in addition to conducting new monitoring under the rule. To be eligible for grandfathering, monitoring results must be equivalent in data quality to monitoring PWSs conduct under today's rule and the PWS must comply with reporting requirements. Details of these requirements follow.

Grandfathered Data Quality Requirements

- Analysis of E. coli samples must meet the analytical method and approved laboratory requirements for source water monitoring under today's rule. PWSs are not required to report E. coli and turbidity data in order to grandfather Cryptosporidium monitoring results, although EPA requests that PWSs report these data if they are available. PWSs that grandfather Cryptosporidium data without associated E. coli and turbidity data are not required to conduct separate monitoring for these parameters when they have satisfied Cryptosporidium monitoring requirements.
- Analysis of Cryptosporidium samples must meet the criteria of a validated version of EPA Method 1622 or 1623, which are described in USEPA 1999a, USEPA 1999b, USEPA 2001e, USEPA 2001f, USEPA 2005c, and USEPA 2005d. The volume analyzed for each sample must meet the criteria described in section IV.J, which are at least 10 L of sample or at least 2 mL of packet pellet volume or as much volume as two approved filters can accommodate before clogging.
- The sampling location must meet the criteria for LT2ESWTR monitoring, as described previously.
- For Cryptosporidium samples, the sampling frequency must be at least monthly and on a regular schedule. The collection of individual samples may deviate from a regular schedule under the same criteria that apply to deviation from LT2ESWTR sampling schedules, as described previously. Additionally, deviations in the sampling frequency of previously collected data are allowed under the following conditions: (1) PWSs may grandfather data where there are gaps in the sampling frequency if the State approves and if the PWS conducts additional monitoring when specified by the State to ensure the data used for bin classification are seasonally representative and unbiased; and (2) PWSs may grandfather data where the sampling frequency varies (e.g., one year of sampling monthly and one year of sampling twice-per-month); monthly average sample concentrations must be used to calculate the bin classification, as described in section IV.B.

Grandfathered Data Reporting Requirements

PWSs that request to grandfather previously collected monitoring results must report the following information by the applicable dates listed in this section. PWSs serving at least 10,000 people must report this information to EPA unless the State approves an alternate procedure for reporting. PWSs serving fewer than 10,000 people must report this information to the State.

PWSs must report that they intend to submit previously collected monitoring results for grandfathering. This report must specify the number of previously collected results the PWS will submit, the dates of the first and last sample, and whether a PWS will conduct additional source water monitoring for initial bin classification. PWSs must report this information no later than three months prior to the date the PWSs is required to start monitoring, as shown in section IV.G.

PWSs must report previously collected monitoring results for grandfathering, along with the required documentation listed in this section, no later than two months after the month the PWS is required to start monitoring, as shown in section IV.G.

- For each sample Cryptosporidium or E. coli result, PWSs must report the applicable data elements in section IV.I.1.
- PWSs must certify to EPA or the State that the reported monitoring results include all results the PWS generated during the time period beginning with the first reported result and ending with the final reported result. This applies to samples that were collected from the sampling location specified for source water monitoring

under this subpart, not spiked, and analyzed using the laboratory's routine process for the analytical methods listed in this section.

• PWSs must certify to EPA or the State that the samples were representative of a plant's source water(s) and the source water(s) have not changed. PWSs must submit to EPA a description of the sampling location(s) for each water treatment plant, which must address the position of the sampling location in relation to the PWS's water source(s) and treatment processes, including points of chemical addition and filter backwash recycle.

• For Cryptosporidium samples, the laboratory or laboratories that analyzed the samples must provide a letter certifying that the quality control criteria specified in the methods listed in this section were met for each sample batch associated with the reported results. Alternatively, the laboratory may provide bench sheets and sample examination report forms for each field, matrix spike, initial precision and recovery (IPR), ongoing precision and recovery (OPR), and method blank sample associated with the reported results.

• If the State determines that a previously collected data set submitted for grandfathering was generated during source water conditions that were not normal for the PWS, such as a drought, the State may disapprove the data. Alternatively, the State may approve the previously collected data if the PWS reports additional source water monitoring data, as determined by the State, to ensure that the overall data set used for bin classification represents average source water conditions for the PWS.

If a PWS submits previously collected data that fully meet the number of samples required for initial source water monitoring and some of the data are rejected due to not meeting the requirements of this section, PWSs must conduct additional monitoring to replace rejected data on a schedule the State approves. PWSs are not required to begin this additional monitoring until at least two months after notification that data have been rejected and additional monitoring is necessary.

h. *Ongoing watershed assessment.* Today's rule includes provisions to assess changes in a PWS's source water quality following initial bin classification. As required by 40 CFR 142.16(b)(3)(i), source water is one of the components that States must address during the sanitary surveys that are required for surface water PWSs. These sanitary surveys must be conducted every 3 years for community PWSs and every 5 years for non-community PWSs. Under today's rule, if the State determines during the sanitary survey or an equivalent source water assessment that significant changes have occurred in the watershed that could lead to increased contamination of the source water by Cryptosporidium, the PWS must take actions specified by the State to address the contamination. These actions may include additional source water monitoring and/or implementing options from the microbial toolbox discussed in section IV.D.

i. *Second round of monitoring.* PWSs must begin a second round of source water monitoring beginning six years after initial bin classification (see compliance dates in section IV.G). If EPA does not modify LT2ESWTR requirements by issuing a new regulation prior to the second round of monitoring, PWSs must carry out this monitoring according to the requirements that apply to the initial round of source water monitoring. PWSs will then be reclassified in LT2ESWTR treatment bins based on the second-round monitoring result. However, if EPA changes the LT2ESWTR treatment bin structure to reflect a new analytical method or new risk information, PWSs will undergo a risk characterization in accordance with the revised rule.

j. *New source monitoring.* A PWS that begins using a new surface water source after the date the PWS is required to conduct source water monitoring under the LT2ESWTR must monitor the new source on a schedule approved by the State. This applies to both new plants that begin operation and previously operating plants that bring a new source on-line after the required monitoring date for the PWS. The State may determine that monitoring should be conducted before a new plant or source is brought on-line or initiated within some time period afterward. The new source monitoring must meet all LT2ESWTR requirements as specified previously in this section. The PWS must also determine its treatment bin classification and comply with any additional Cryptosporidium treatment requirements based on the monitoring results on a schedule approved by the State.

2. Background and Analysis

Monitoring requirements in today's rule are designed to ascertain Cryptosporidium levels with suitable accuracy for making treatment bin classifications and in a time frame that does not delay the installation of Cryptosporidium treatment where needed. The following discussion summarizes the basis for monitoring requirements with respect to sampling parameters and frequency, sampling location, sampling schedule, monitoring plants that operate for only part of the year, failing to monitor, grandfathering previously collected data, ongoing watershed assessment, and the second round of monitoring. Most of these requirements were part of the August 11, 2003, proposal for today's final rule, and supporting analyses are presented in greater detail in the proposal (USEPA 2003a). Differences from proposed requirements are noted in the following discussion where applicable.

a. *Sampling parameters and frequency.* The requirements in today's final rule for the parameters and frequency of source water monitoring are unchanged from those in the proposed rule (USEPA 2003a), with the exception of an additional option for lower frequency Cryptosporidium sampling by small PWSs. These requirements reflect recommendations by the Stage 2 M-DBP Advisory Committee. They are designed to ensure a low potential for misclassification in assigning PWSs to Cryptosporidium treatment bins. The supporting analyses are summarized as follows for Cryptosporidium and indicator (E. coli) monitoring:

Cryptosporidium Monitoring

EPA analyzed bin misclassification rates for different Cryptosporidium monitoring programs by evaluating the likelihood of two types of errors:

(1) A PWS with a true mean Cryptosporidium concentration of 0.5-log (i.e., factor of 3.2) above a bin boundary is incorrectly assigned to a lower bin (false negative) and

(2) A PWS with a true mean concentration of 0.5-log below a bin boundary is incorrectly assigned to a higher bin (false positive).

The first type of error, a false negative, could lead to PWSs not providing an adequate level of treatment while the second type of error, a false positive, could lead to PWSs incurring additional costs for unnecessary treatment.

EPA evaluated false positive and false negative rates for monitoring programs that differed based on the number of samples collected and the calculation used to determine the bin classification. The analysis accounted for the sample volume assayed, variation in source water Cryptosporidium occurrence, variation in analytical method recovery, and other factors.

Results of this analysis indicate that PWSs must collect at least 24 samples in order to keep the likelihood of both false positives and false negatives at five

percent or less. Under a monitoring program involving fewer samples, such as eight or twelve, a very conservative calculation for bin classification would be required to achieve a low false negative rate (e.g., bin classification based on the maximum or second highest sample concentration). However, such an approach would result in false positive rates in the range of 50 to 70 percent. Conversely, collecting more than 24 samples can further reduce false positive and false negative rates, albeit to a small degree. See the proposed LT2ESWTR for additional details on this analysis (USEPA 2003a).

Based on the results of this analysis, EPA concluded that PWSs operating year-round should collect at least 24 samples when they monitor for Cryptosporidium. This number of samples ensures a high likelihood of appropriate bin classification. Today's rule does not allow bin classification based on fewer samples (except in the case of PWSs operating only part of the year) as this would involve unacceptably high false positive or false negative rates and would, therefore, be an inappropriate basis to determine Cryptosporidium treatment requirements. EPA believes, though, that PWSs should have the choice to collect more than 24 samples to further improve the accuracy of bin classification, and today's rule allows this.

In regard to the time frame for LT2ESWTR monitoring, the Agency considered the trade-off between monitoring over a long period to better capture temporal fluctuations and the desire to prescribe additional treatment quickly to PWSs with higher Cryptosporidium levels. Today's rule requires large PWSs to evaluate their source water Cryptosporidium levels using two years of monitoring. This will account for some degree of yearly variability, without significantly delaying additional public health protection where needed.

Because many small PWSs will monitor for E. coli for one year before monitoring for Cryptosporidium, today's rule allows two options. Small PWSs can collect 24 Cryptosporidium samples over just one year (resulting in a total of two years of source water monitoring when E. coli monitoring is considered) or they can spread their 24 Cryptosporidium samples over two years. Spreading the Cryptosporidium monitoring over two years will reduce the monitoring costs a PWS incurs in a single year but will not push back the treatment compliance deadline. This allowance for small PWSs to monitor for Cryptosporidium over two years is a change from the proposal (USEPA 2003a). It stems from recognition of the benefit this approach will provide to some small PWSs in budgeting for monitoring.

Indicator Monitoring

Due to the relatively high cost of analyzing samples for Cryptosporidium, the Advisory Committee and EPA investigated indicators that are less costly to analyze to determine if any could be used in place of Cryptosporidium monitoring. No indicators were identified that correlated strongly with Cryptosporidium and could fully substitute for Cryptosporidium monitoring for determining treatment bin classifications. However, this investigation did identify an indicator, E. coli, that can be used to identify some of the water sources that are unlikely to exceed a Cryptosporidium level of 0.075 oocysts/L—the level at which filtered PWSs must provide additional treatment under the LT2ESWTR.

Data from the ICR and ICRSS were used in the investigation of indicators. With these data, E. coli performed the best in identifying sources with low Cryptosporidium levels. In addition, analyzing plants separately based on source water type was necessary due to a different relationship between E. coli and Cryptosporidium in reservoir/lake sources compared to flowing stream sources.

The analysis of E. coli concentrations that could trigger Cryptosporidium monitoring was based on false negative and false positive rates. For this indicator, false negatives occur when sources do not exceed the E. coli trigger value but exceed a Cryptosporidium level of 0.075 oocysts/L. False positives occur when sources exceed the E. coli trigger value but do not exceed a Cryptosporidium level of 0.075 oocysts/L. The false negative rate is critical because it characterizes the ability of the indicator to identify those plants with higher Cryptosporidium levels that should conduct Cryptosporidium monitoring to determine if additional treatment is needed.

For plants with flowing stream sources, a mean E. coli trigger concentration of 50/100 mL produced zero false negatives for both ICR and ICRSS data sets. This means that in these data sets, all plants that exceeded mean Cryptosporidium concentrations of 0.075 oocysts/L also exceeded the E. coli trigger concentration. The false positive rate for this trigger concentration was near 50 percent, meaning it was not highly specific in targeting only those plants with high Cryptosporidium levels. However, at a higher E. coli trigger concentration, such as 100/100 mL, the false negative rate increased without a significant reduction in the false positive rate.

For plants with lake or reservoir sources, a mean E. coli trigger of 10/100 mL resulted in a false negative rate of 20 percent with ICR data and 67 percent with ICRSS data. While this false negative rate in the ICRSS data set appears high, it is based on just three plants in this survey that used a reservoir/lake source and had a mean Cryptosporidium level above 0.075 oocysts/L. With a lower E. coli trigger concentration, such as 5/100 mL, the number of false negatives in both data sets decreased by one plant, but the false positive rate increased from 20 to 40 percent.

After evaluating these results, the Advisory Committee recommended that all large PWSs monitor for Cryptosporidium, rather than using E. coli in a screening analysis. EPA concurred with this recommendation because it achieves the highest certainty that these PWSs will be classified in the correct Cryptosporidium treatment bin and provide the appropriate level of public health protection. In addition, the Advisory Committee recommended and today's rule requires that large filtered PWSs collect E. coli and turbidity samples along with Cryptosporidium. EPA will use these data to confirm or, if necessary, further refine the use of E. coli and possibly turbidity as indicators for monitoring by small filtered PWSs.

Cryptosporidium monitoring places a relatively greater economic burden on small PWSs, and EPA will have additional E. coli and Cryptosporidium data from large PWS monitoring prior to the initiation of small PWS monitoring. Based on these considerations and the available data on E. coli as an indicator of sources with lower Cryptosporidium levels, the Advisory Committee recommended that small filtered PWSs initially monitor for E. coli for one year as a screening analysis. Biweekly sampling (i.e., 1 sample every two weeks) for E. coli is required to achieve high confidence in the results, since no additional monitoring is required if the E. coli level is less than the trigger value. Mean E. coli concentrations above 10 and 50/100 mL trigger Cryptosporidium monitoring in PWSs using reservoir/lake and flowing stream sources, respectively.

EPA concurred with these recommendations by the Advisory Committee and believes they achieve an appropriate balance between enhancing

public health protection and reducing the economic impact of today's rule on small PWSs. Survey data indicate that approximately 75 to 80 percent of small PWSs will not exceed the E. coli trigger values and, consequently, will not be required to monitor for Cryptosporidium. Because E. coli is far less costly to analyze than Cryptosporidium (costs listed in USEPA 2005a), this approach will significantly reduce the burden of today's rule for these PWSs. Further, EPA will review indicator data from large PWS monitoring and, if appropriate, issue guidance to States on alternative indicator triggers prior to when small PWSs begin monitoring. Today's rule allows States to approve alternative approaches to indicator monitoring for small PWSs.

EPA could not identify an indicator screening analysis for unfiltered PWSs. As described in section IV.C, a mean Cryptosporidium concentration of 0.01 oocysts/L determines whether unfiltered PWSs are required to provide 2- or 3-log Cryptosporidium inactivation. No E. coli concentration was effective in determining whether PWSs were likely to fall above or below this level. Consequently, today's rule requires all unfiltered PWSs to monitor for Cryptosporidium, unless they choose to provide 3-log Cryptosporidium inactivation.

b. Sampling location. The requirements in today's final rule for the source water sample collection location are similar to those in the proposed rule (USEPA 2003a). They are designed to achieve two objectives: (1) Characterize the influent water to the treatment plant at the time each sample is collected and (2) ensure that samples are not affected by treatment chemicals that could interfere with Cryptosporidium analysis.

The first objective is the basis for requiring PWSs that use multiple sources to either analyze a blended source sample or calculate a weighted average of sources that reflects the influent at the time of sample collection. It is also the reason that PWSs are required to sample after certain pretreatment processes like bank filtration (described in section IV.D) that do not involve chemical addition.

The second objective is why PWSs are generally required to sample upstream of chemical addition and prior to backwash addition (for PWSs that recycle filter backwash). However, EPA recognizes that in some situations, sampling prior to chemical addition will not be feasible and discontinuing chemical addition for a period of time prior to sampling will not be advisable. This situation could occur when a treatment chemical is added at an intake that is difficult to access. Further, some treatment chemicals may not interfere with Cryptosporidium analyses when present at very low levels. Consequently, today's rule allows States to approve PWSs sampling after chemical addition when the State determines that collection prior to chemical treatment is not feasible and the treatment chemical is not expected to interfere with the analysis of the sample.

EPA believes that States should review source water monitoring locations for their PWSs. State review of monitoring locations will ensure that PWSs collect source water samples at the correct location to determine the appropriate level of public health protection. Consequently, today's rule requires PWSs to report a description of their monitoring location to the State. This requirement is a change from the proposed rule, which did not require PWSs to report a description of their sampling location (USEPA 2003a). This change reflects public comment on the proposal, as described later, which strongly supported State review of monitoring locations. If a PWS does not hear back from the State by the time it is scheduled to begin sampling, it may assume that its monitoring location is acceptable.

c. *Sampling schedule.* The requirement in today's final rule that PWSs must develop a schedule for sample collection before the start of monitoring was part of the proposal (USEPA 2003a). This requirement will help to ensure that monitoring determines the mean concentration of Cryptosporidium in the treatment plant influent. To achieve this objective, the timing of sample collection must not be adjusted in response to fluctuations in water quality—for example, the avoidance of sampling when the influent water is expected to be of poor quality.

EPA believes that the 5-day window for sample collection and associated allowances for sampling outside this window provide sufficient flexibility. If circumstances arise that prevent the PWS from sampling within the scheduled 5-day window, such as a weather event or plant emergency, the PWS must collect a sample as soon as feasible. In this case, feasibility includes both the ability of the PWS to safely collect a sample and the availability of an approved laboratory to conduct the analysis within method specifications. In addition, today's rule allows States to authorize a different date for collecting the delayed sample. Such an authorization may be appropriate in cases where sampling is significantly delayed and collecting the delayed sample during the same time period in the following year of monitoring is preferable.

PWSs that collect a sample as scheduled but are unable to have the sample analyzed as required due to problems like shipping or laboratory analysis must collect a replacement sample within 21 days of receiving information that one is needed, unless the PWS demonstrates that collecting a replacement sample within this time frame is not feasible. This time frame is a minor change from the proposal, which allowed only 14 days for resampling (USEPA 2003a), and it provides greater flexibility for scheduling replacement samples. Information that resampling is needed includes information the PWS acquires directly, as well as notice from the shipping company, laboratory, State, or EPA. Today's rule allows States to authorize an alternative date for collection of the replacement sample. This may be needed for resampling to occur during the same conditions as the originally scheduled sample.

If collecting a sample was feasible but the PWS failed to do so, EPA believes that the PWSs must develop a revised sampling schedule and submit it to the State. This will allow for State consultation regarding the reason for the missed sample(s) and strategies for the PWS to complete the required monitoring.

d. *Plants operating only part of the year.* The proposed LT2ESWTR did not include distinct monitoring requirements for plants that operate only part-year. However, EPA requested comment in the proposal on an approach to plants that operate only part-year that is similar to the requirements in today's final rule (USEPA 2003a).

Monitoring requirements for plants that operate only part-year derive from three considerations: (1) A PWS should sample only during the months when a treatment plant operates; (2) the mean Cryptosporidium level used for bin classification can be determined with fewer samples in plants that operate only part-year because source water quality typically varies less during the shorter operating period; and (3) a minimum number of samples is necessary to classify any plant in an LT2ESWTR bin with high confidence.

The basis for the first consideration is straightforward. Source water monitoring under the LT2ESWTR is used to establish treatment requirements, and these should be based

on the water quality when a plant is in operation. The rationale for the second and third considerations stems from analyses, similar to those described previously, of potential misclassification rates in assigning plants to LT2ESWTR treatment bins.

Source water variability is one factor that influences the number of samples needed to accurately classify plants in LT2ESWTR treatment bins. As variability increases, more samples are needed to determine the mean Cryptosporidium level with high confidence. EPA does not have data on source water variability specifically in plants that operate only part-year. However, survey data show that pathogen levels vary seasonally, and plants operating part-year will generally experience less variability during a given year than plants operating year-round. Consequently, fewer samples are typically needed to determine the mean Cryptosporidium level during the period of operation for a part-year plant.

Nevertheless, even when a plant operates for only a few months per year and source water exhibits little variability, a minimum number of samples is necessary for bin classification. This is due to the relatively low sample volume, variable method recovery, nonhomogeneous distribution of Cryptosporidium in water, and other factors that limit the accuracy of any individual sample for characterizing the source water. Data suggest that for plants operating for six months per year or less, collecting a minimum of six samples per year over two years may allow bin classification with comparable accuracy to that achieved by year-round plants sampling monthly (USEPA 2005a).

Based on these considerations, today's rule requires similar source water monitoring for plants that operate only part-year during their months of operation as is required for year-round plants. However, if the plant is required to monitor for Cryptosporidium and operates for six months or less, the PWS must collect at least six Cryptosporidium samples per year over two years.

e. *Failing to monitor.* Requirements for PWSs that fail to conduct source water monitoring are based on the need for PWSs to determine a Cryptosporidium bin classification and provide the appropriate level of public health protection within the compliance time frame. The LT2ESWTR proposal required PWSs that did not complete all source water monitoring requirements to meet the requirements of the highest treatment bin (USEPA 2003a). In today's final rule, EPA has significantly changed requirements from those in the proposal for PWSs that fail to monitor. These changes are intended to give States more flexibility in working with PWSs to fulfill monitoring requirements and ensure they achieve the appropriate Cryptosporidium treatment level.

For most monitoring and testing procedure violations under the LT2ESWTR, PWSs must provide a Tier 3 public notification, which is standard for this type of violation under an NPDWR. However, if a PWS fails to collect three or more Cryptosporidium samples, the violation is elevated to a Tier 2 special public notice. The reason for elevating the public notice at this point is the persistence of the violation and the difficulty the PWS will have in collecting the required number of samples for bin classification by the compliance date. Section IV.H provides further details on public notice requirements of the LT2ESWTR.

As described in section IV.G, today's rule requires bin classification within six months following the end of the monitoring period specified for the PWS. This six-month period provides some opportunity for collecting and analyzing missed samples. The number of samples that can be made up in this period is limited, though, due to the need for samples to be evenly distributed throughout the year, as well as for PWSs and States to spend time during this period evaluating monitoring results to determine bin classification. In consideration of these factors, EPA believes that elevating the public notice when a PWS has missed three or more Cryptosporidium samples is appropriate. This violation will end when the State determines that the PWS has begun sampling on a schedule to collect the required number of samples.

Failure by a PWS to collect the required number of Cryptosporidium samples for bin classification by the compliance date is a treatment technique violation with a required Tier 2 public notice. This violation reflects the inability of the PWS to determine and comply with its Cryptosporidium treatment requirements under the LT2ESWTR and provide the appropriate level of public health protection. The violation ends when the State determines that the PWS is carrying out a monitoring plan that will lead to bin classification. A PWS that has already provided a Tier 2 public notice for missing three sampling dates and is successfully meeting a State-approved sampling schedule is not required to issue another public notice for missing the bin classification date. Alternatively, the PWS can choose to provide the highest level of Cryptosporidium treatment required under the rule, which is 5.5-log for filtered PWSs and 3-log for unfiltered PWSs.

f. *Grandfathering previously collected data.* Requirements for grandfathering previously collected monitoring data in today's final rule are similar to those in the proposal (USEPA 2003a). These requirements are based on the principle that to be eligible for grandfathering, previously collected data must be equivalent in quality to data that will be collected under the rule.

The Stage 2 M–DBP Advisory Committee recommended that EPA accept previously collected Cryptosporidium data that are ''equivalent in sample number, frequency, and data quality (e.g. volume analyzed, percent recovery) to data that would be collected under the LT2ESWTR * * * to determine bin classification in lieu of further monitoring'' (USEPA 2000a). The Advisory Committee recognized that accepting previously collected data could have a number of benefits, including early determination of LT2ESWTR compliance needs, increasing laboratory capacity, and allowing PWSs to determine their bin classification using a larger, and potentially more representative, data set.

To ensure equivalent data quality, today's rule requires that grandfathered data meet the same requirements for analytical methods, sampling location, and sample volume as data collected under the rule. PWSs must not selectively report monitoring results for grandfathering. Further, grandfathered Cryptosporidium data must generally be collected at least monthly and on a regular schedule, with the same provisions for delayed or replacement samples as allowed for regular monitoring. Today's final rule differs from the proposal, however, in making allowances for use of previously collected data where irregularities or gaps in the sampling frequency occur.

EPA recognizes that when PWSs collected Cryptosporidium data prior to the proposed or final LT2ESWTR, there may have been months when a PWS either failed to collect or lost a sample due to problems with equipment, transportation, laboratory analysis, or other reasons. If the PWS did not collect a replacement sample, gaps in the previously collected data set occurred. EPA believes that grandfathering of such a data set may be appropriate despite these gaps if the PWS conducts additional monitoring, as necessary, to ''fill-in'' gaps and ensure that the data set is unbiased. Consequently, today's rule allows grandfathering of data with

gaps in the sampling frequency if approved by the State.

In addition, if the frequency of sampling in a previously collected data set varies, EPA believes the data could still be appropriate for use in bin classification. For example, a PWS might have sampled for Cryptosporidium once per month for a number of months and then increased the sampling frequency to twice per month. Today's rule allows the use of such a data set. However, to avoid bias, the PWS must calculate a monthly average for each month of sampling and then determine the bin classification using these monthly averages, rather than the individual sample concentrations.

Today's rule requires PWSs that plan to grandfather monitoring data to notify EPA or the State regarding the number and time span of sample results no later than three months prior to when the PWS must begin monitoring. The timing for submission of this notice is concurrent with the submission of a sampling schedule. This notification is necessary for the State to determine that a PWS is not required to submit a sampling schedule (when a PWS will fully comply with initial monitoring through grandfathering) or that a sampling schedule may include less than the full number of required samples (when a PWS will conduct new monitoring in conjunction with grandfathering to complete a data set). Further, this notice will assist EPA and States in determining the resources necessary to ensure timely review of grandfathered data.

PWSs must submit all monitoring results for grandfathering to EPA or the State, along with required supporting documentation, no later than two months after the PWS is required to begin monitoring. This timing will allow a PWS to continue collecting data for grandfathering until the month the PWS is required to begin monitoring under today's rule, plus an additional two months for sample analysis and compilation of the data for submission.

This reporting deadline for grandfathering monitoring results is a change from the proposed rule. In the proposal, a PWS that intended to grandfather data in lieu of conducting new monitoring under the rule had to submit its grandfathered results no later than four months prior to when the PWS was otherwise required to begin monitoring under the rule. This proposed approach had the shortcoming that a PWS could not complete its monitoring for grandfathering within this four month period. In today's final rule, a PWS may continue monitoring for grandfathering all the way until the date when the PWS must begin monitoring under the rule, if necessary. PWSs that conclude their monitoring for grandfathering earlier may submit the data at an earlier date.

g. *Ongoing watershed assessment.* Treatment requirements under the LT2ESWTR are based on source water quality. Consequently, today's rule requires watershed assessment and, as described in the next section, a second round of monitoring following initial bin classification to determine if source water quality has changed to the degree that the treatment level should be modified. These requirements are unchanged from those in the proposed LT2ESWTR (USEPA 2003a), with the exception of an allowance for States to use programs other than the sanitary survey to assess changes in the watershed.

Today's rule leverages the existing requirement for States to perform sanitary surveys on surface water PWSs. During the source water review in the sanitary survey, today's rule requires States to determine if significant changes have occurred in the watershed that could lead to increased contamination by Cryptosporidium. The State can also choose to make this determination through an equivalent review of the source water under a program other than the sanitary survey, such as a Source Water Protection Assessment. If the State determines that significant changes have occurred, the State may specify that the PWS conduct additional source water monitoring or treat the potential contamination. This approach allows the PWS and State to respond to a significant change in source water quality prior to initiating a second round of monitoring or any time thereafter.

h. *Second round of monitoring.* A more rigorous reassessment of the source water occurs through a second round of monitoring that begins six years after initial bin classification. If EPA does not develop and finalize modifications to the LT2ESWTR prior to the date when PWSs must begin the second round of monitoring, then this second round must conform to the same requirements that applied to the initial round of monitoring. PWSs may be classified in a different treatment bin, depending on the results of the second round of monitoring.

The Stage 2 M–DBP Advisory Committee recommended that EPA initiate a stakeholder process several years prior to the second round of monitoring to review new information and determine if today's rule should be modified. If the Agency modifies the LT2ESWTR, the second round of monitoring would potentially involve a new analytical method and a different treatment bin structure.

3. Summary of Major Comments

Public comment on the August 11, 2003, LT2ESWTR proposal generally supported the use of source water monitoring to determine additional treatment requirements. The following discussion summarizes major comments and EPA's responses in regard to sampling parameters and frequency, sampling location, sampling schedule, monitoring plants that operate only part-year, failing to monitor, providing treatment instead of monitoring, grandfathering previously collected data, ongoing source water assessment, second round of monitoring, and new source monitoring.

a. *Sampling parameters and frequency.* Most commenters supported the proposed requirements for large PWSs to sample monthly for Cryptosporidium, as well as for E. coli and turbidity in filtered PWSs, for 24 months. Alternatives recommended by some commenters included ending monitoring after one year if no oocysts are detected, allowing large PWSs to use an E. coli screening analysis to determine if Cryptosporidium monitoring is necessary, and using watershed data to determine treatment needs instead of source water monitoring.

In response, EPA continues to believe that large PWSs should complete 24 months of Cryptosporidium monitoring, regardless of the first-year results, in order to capture a degree of annual variability in Cryptosporidium occurrence. Moreover, for the reasons discussed previously in this preamble, EPA continues to support the Advisory Committee recommendation that all large PWSs should monitor for Cryptosporidium, rather than use the E. coli screening analysis. EPA is not aware of studies that support the use of other watershed data in place of Cryptosporidium monitoring to determine treatment needs.

Regarding requirements for small PWSs, most commenters supported the E. coli screening analysis for small filtered PWSs. Several commenters recommended more options for Cryptosporidium monitoring by small PWSs, such as allowing monitoring to be spread over two years, instead of the one year required in the proposal, or allowing fewer samples. EPA agrees that budgeting for Cryptosporidium monitoring by some small PWSs will be easier if it is spread over two years, and today's rule allows this as an option.

However, based on the analysis of false negative and false positive rates described previously, EPA continues to believe that at least 24 Cryptosporidium samples are necessary to determine the appropriate bin classification for year-round plants.

b. *Sampling location.* With respect to sampling location requirements, several commenters recommended that PWSs be allowed to collect samples either before or after pretreatment processes. These commenters stated that the chemicals used in pretreatment processes are unlikely to affect the analysis of Cryptosporidium oocysts at typical concentrations. Further, where sampling is conducted prior to a pretreatment process like presedimentation, commenters supported allowing PWSs to receive additional treatment credit for the process.

In response, EPA continues to believe that common pretreatment chemicals like oxidants and coagulants have the potential to adversely affect the performance of Cryptosporidium analytical methods. Consequently, today's rule requires that in most cases, PWSs must sample upstream of chemical addition. Where PWSs sample prior to pretreatment processes like presedimentation with coagulation, they are eligible to receive additional treatment credit for the process. However, if sampling prior to chemical addition is not feasible for a particular plant and the treatment chemical is present at a very low level that is unlikely to interfere with sample analysis, the State may approve sampling after chemical addition.

Many commenters recommended that States approve sampling locations for their PWSs. Commenters indicated that State review and approval of monitoring plans will help to prevent confusion and PWSs potentially sampling at an incorrect location. EPA agrees with these commenters and has established a requirement in today's rule for PWSs to report a description of the sampling location to the State. If a PWS does not hear back from the State by the time it is scheduled to begin sampling, it may assume that its monitoring location is acceptable.

c. *Sampling schedule.* In regard to sampling schedule requirements, several commenters requested that PWSs be given a time window larger than 5 days around scheduled sampling dates to collect samples. Recommended alternatives included a 7 or 9-day window, or only requiring that PWSs collect a sample within a specified month. In addition, commenters identified situations that interfere with sample collection, such as plant interruptions and laboratory or transportation problems, and noted that some of these are outside the conditions under which the proposal allowed a PWS to collect a delayed or replacement sample without penalty.

In response, EPA continues to believe that for routine sample collection, a 5-day window provides sufficient flexibility, given that PWSs will pick the sampling days and can schedule around holidays, weekends, and other times when sampling would be problematic. However, today's rule allows PWSs to sample outside of this window without penalty if necessary due to unforeseen conditions. Further, if a PWS collects a sample but is unable to have it analyzed due to problems with equipment, transportation or the laboratory, today's rule allows the PWS to collect a replacement sample without penalty.

In regard to the time frame for collecting missed or replacement samples, commenters recommended a number of approaches. These include adding extra sampling days to the original sampling schedule, which a PWS could then use in the event of missed sampling dates, and allowing PWSs to collect make-up samples either immediately after the scheduled sampling date or at the end of the monitoring period.

In general, EPA considers it preferable for PWSs to collect missed or replacement samples as close as is feasible to scheduled sampling dates. However, if there is a significant delay with respect to the original sampling date, collecting make-up samples at an alternate time may be appropriate to ensure that sampling results are seasonally representative. Therefore, today's rule requires PWSs to collect a missed sample as close as is feasible to the scheduled sampling date, and to collect replacement samples within 21 days of receiving information that one is needed, unless doing so within this time frame is not feasible. However, the State can authorize alternative sampling dates so that monitoring is not seasonally biased. This could include sampling during the same time in the following year, if the missed sample occurred during the first year of monitoring, or sampling after the end of the scheduled monitoring period.

d. *Plants operating only part of the year.* Commenters on monitoring requirements for surface water plants that operate for only part of the year generally recommended that sampling occur only during the period of operation. However, several different options were put forward for how the sampling be conducted. Some commenters recommended a minimum of 12 samples per year for two years distributed evenly over the period that the plant operates. Others suggested allowing the PWS to collect the required number of samples over a longer time period in order to limit the frequency of required samples when the plant is operating. Several commenters said that State input is critical to determining the appropriate monitoring period since States may have historical knowledge of plant operating practices.

In response, EPA agrees that monitoring of plants that operate only part-year under today's rule should be conducted only during months when the plant is operating, unless the State determines that a longer monitoring period is appropriate due to historical operating practices. Further, plants that operate only part-year should maintain the same sampling frequency as plants operating year-round, with the exception that plants monitoring for Cryptosporidium must collect at least six samples per year to allow for appropriate bin classification. EPA does not believe extending monitoring over more years in plants that operate only part-year is appropriate, as this would delay the installation of additional treatment where needed.

e. *Failing to monitor.* Most commenters opposed automatically classifying PWSs in the highest treatment bin (Bin 4) if they fail to complete required monitoring, as the proposed rule stipulated. Commenters suggested alternative approaches, such as giving States the flexibility to address missed samples using current enforcement mechanisms, classifying a PWS only one level higher than the bin determined by the collected data, allowing an additional year of sampling, and allowing States to use other information (e.g., sanitary surveys, other monitoring data) to aid in the classification. A few commenters, however, supported Bin 4 classification for PWSs that fail to monitor, on the basis that any other approach would create an incentive for PWSs to stop testing if poor water quality is suspected.

EPA agrees that States should have flexibility in dealing with PWSs that fail to monitor. Further, providing the highest level of treatment may not be in the best interests of consumers where a PWS has minor problems in carrying out source water monitoring. However, EPA also believes that violations for monitoring failures must reasonably ensure that PWSs complete monitoring as required to determine a bin classification within the compliance

date. Failure to do so would potentially compromise public health protection.

Based on these considerations, EPA has not established an automatic Bin 4 classification for monitoring failures under today's rule. Rather, if a PWS misses three or more Cryptosporidium samples, this persistent violation requires a Tier 2 public notice (other violations require a Tier 3 notice). Further, if a PWS is unable to determine a bin classification by the compliance date due to failure to collect the required number of Cryptosporidium samples, this is a treatment technique violation with a required Tier 2 public notice (unless the PWS has already issued a Tier 2 notice for missing 3 Cryptosporidium samples and is monitoring on a State-approved schedule). These violations last until the State determines that a PWS has begun monitoring on a schedule that will lead to bin classification or the PWS agrees to install treatment instead of monitoring.

f. *Providing treatment instead of monitoring.* Commenters supported the option for a PWS to provide the highest level of Cryptosporidium treatment required under today's rule rather than conducting source water monitoring. Several commenters recommended that a PWS should be allowed to take this option after having initiated monitoring. EPA agrees, and today's rule allows a PWS to stop monitoring at any time by notifying the State that it will provide 5.5-log Cryptosporidium treatment for filtered PWSs or 3-log Cryptosporidium inactivation for unfiltered PWSs by the compliance deadline specified in section IV.G.

g. *Grandfathering previously collected data.* With respect to grandfathering previously collected data, many commenters expressed concern with a proposed requirement that samples must have been collected in equal time intervals. Commenters stated that although PWSs may have sampled on a regular schedule, previously collected data sets are likely to have gaps due to samples rejected for method QC violations or periods when the PWS was unable to collect a sample. In addition, there are instances where PWSs have changed the frequency of sampling, such as from monthly to twice per month.

EPA agrees that if a PWS has collected samples according to a regular schedule and met other data quality standards, then rejecting a large data set due to isolated gaps in the sampling frequency would be inappropriate. Consequently, today's rule allows States to approve grandfathering of previously collected data with omissions in the sampling interval, provided the PWS conducts additional monitoring if required by the State to ensure the data set is seasonally representative. Further, PWSs may grandfather previously collected data sets in which the sampling frequency varies, as long as samples were collected at least monthly. In this situation, PWSs must use monthly average concentrations, rather than individual sample concentrations, for bin classification.

With respect to data quality standards, such as meeting analytical method QC criteria, sampling at the correct location, and analyzing the minimum sample volume, several commenters stated that EPA should apply the same acceptance standards to previously collected data as are applied to data collected under today's rule. Other commenters, though, suggested that States should have the flexibility to accept previously collected data that deviate from the data quality standards for monitoring under the rule. These commenters stated that such data sets might include samples collected over a longer period of time and may reflect more worst-case weather events.

In response, EPA believes that data quality standards should be uniformly applied under today's rule, so that previously collected data should not be held to a lower standard than new data or evaluated differently from State to State. The requirements in today's rule with respect to Cryptosporidium analytical methods and minimum sample volume reflect recommendations of the Advisory Committee, which also recommended that the same data quality standards be applied for grandfathering. Further, because today's rule allows PWSs to collect make-up samples to address gaps in previously collected data sets, PWSs will have the opportunity to collect make-up samples for results that are rejected due to data quality standards without losing an entire data set.

In regard to notification of the acceptability of data for grandfathering, commenters recommended that if previously collected data submitted by a PWS are rejected, the PWS should have at least two months between notification and the date new monitoring must be initiated. These two months will give the PWS time to address rejection of the data and prepare for sampling. EPA agrees with this recommendation. Under today's rule, if a PWS properly submits a complete data set for grandfathering and the PWS must conduct new monitoring due to rejection of the data, the PWS has at least two months following notification by the State to initiate sampling.

h. *Ongoing watershed assessment.* Commenters asked for greater flexibility in the requirement for States to determine whether there have been significant changes in the watersheds of their PWSs that could lead to increased contamination. The proposed rule specified that States must make this determination during sanitary surveys. However, several commenters noted that some States perform source water protection assessments on the same frequency as sanitary surveys, and these detailed assessments might be a better mechanism to monitor changes in the watershed. EPA agrees and today's rule allows States to determine whether significant changes have occurred in the watershed through either a sanitary survey or an equivalent review of the source water under another program.

i. *Second round of monitoring.* Some commenters supported the proposed requirement for a second round of source water monitoring, but most opposed requiring it for all PWSs. These commenters recommended that States should be authorized to use sanitary surveys, source water assessments, ambient water quality data, treatment plant data, and other information to determine if a second round of monitoring is necessary for a PWS. Some commenters suggested that EPA fund research to allow the use of finished water monitoring as the determinant for treatment requirements in a second round of monitoring.

In response, EPA continues to believe that PWSs should conduct a second round of monitoring to determine if the level of treatment required as a result of the first round of monitoring is still appropriate. Consequently, today's rule requires this. However, EPA agrees that prior to a second round of monitoring, the Agency should evaluate the results of the first round of monitoring, along with whatever new information is available on Cryptosporidium analytical methods, risk, and other relevant issues. If EPA determines that there should be changes to the requirements for a second round of monitoring in today's rule, the Agency will issue a new rule establishing those changes.

j. *New source monitoring.* EPA requested comment in the proposal on monitoring requirements for new plants and sources (USEPA 2003a). Most commenters recommended that new plants and sources undergo monitoring equivalent to that required for existing plants and sources, and suggested that States should have discretion to determine when monitoring should take place. EPA agrees with these recommendations and today's rule requires PWS to conduct source water

monitoring for new plants and sources on a schedule approved by the State. This schedule must include dates for the PWS to determine its treatment bin classification and, if necessary, comply with additional Cryptosporidium treatment requirements.

B. Filtered System Cryptosporidium Treatment Requirements

1. Today's Rule

Today's rule requires filtered PWSs using surface water or GWUDI sources to provide greater levels of treatment if their source waters have higher concentrations of Cryptosporidium. Specifically, filtered PWSs are classified in one of four treatment bins based on results from the source water monitoring described in the previous section. PWSs classified in the lowest concentration bin are subject to no additional treatment requirements, while PWSs assigned to higher concentration bins must reduce Cryptosporidium levels beyond IESWTR and LT1ESWTR requirements. All PWSs must continue to comply with the requirements of the SWTR, IESWTR, and LT1ESWTR, as applicable.

This section addresses procedures for classifying filtered PWSs in Cryptosporidium treatment bins and the treatment requirements associated with each bin. Section IV.D presents the treatment and control options, collectively termed the ''microbial toolbox,'' that PWSs must use to meet additional Cryptosporidium treatment requirements under today's rule.

a. *Bin classification.* After completing initial source water monitoring, filtered PWSs must calculate a Cryptosporidium bin concentration for each treatment plant where Cryptosporidium monitoring is required. This Cryptosporidium bin concentration is used to classify filtration plants in one of the four treatment bins shown in Table IV.B–1.

TABLE IV.B–1.—BIN CLASSIFICATION TABLE FOR FILTERED PWSS

For PWSs that are:	with a Cryptosporidium bin concentration of . . .	The bin classification is . . .
* * * required to monitor for Cryptosporidium	less than 0.075 oocysts/L	Bin 1.
	0.075 oocysts/L or higher, but less than 1.0 oocysts/L	Bin 2.
	1.0 oocysts/L or higher, but less than 3.0 oocysts/L	Bin 3.
	3.0 oocysts/L or higher	Bin 4.
* * * serving fewer than 10,000 people and NOT required to monitor for Cryptosporidium [1].	NA	Bin 1.

[1] Filtered PWSs serving fewer than 10,000 people are not required to monitor for Cryptosporidium if they monitor for E. coli and demonstrate a mean concentration of E. coli less than or equal to 10/100 mL for lake/reservoir sources or 50/100 mL for flowing stream sources or do not exceed an alternative State-approved indicator trigger (see section IV.A.1).

In general, the Cryptosporidium bin concentration is calculated by averaging individual sample results from one or more years of monitoring. Specific procedures vary, however, depending on the frequency and duration of monitoring. These procedures are as follows:

(1) For PWSs that collect a total of at least 24 but not more than 47 Cryptosporidium samples over two or more years, the Cryptosporidium bin concentration is equal to the highest arithmetic mean of all sample concentrations in any 12 consecutive months of Cryptosporidium monitoring.

(2) For PWSs that collect a total of at least 48 samples, the Cryptosporidium bin concentration is equal to the arithmetic mean of all sample concentrations.

(3) For PWSs that serve fewer than 10,000 people and monitor for Cryptosporidium for only one year (i.e., collect 24 samples in 12 months), the Cryptosporidium bin concentration is equal to the arithmetic mean of all sample concentrations.

(4) For PWSs with plants that operate only part-year that monitor for less than 12 months per year, the Cryptosporidium bin concentration is equal to the highest arithmetic mean of all sample concentrations during any year of Cryptosporidium monitoring.

In data sets with variable sampling frequency, PWSs must first calculate an arithmetic mean for each month of sampling and then apply one of these four procedures using the monthly mean concentrations. As described in section IV.A, PWSs may grandfather previously collected Cryptosporidium data where the sampling frequency varies (e.g., one year of monthly sampling and one year of twice-per-month sampling).

Filtered PWSs serving fewer than 10,000 people are not required to monitor for Cryptosporidium if they demonstrate a mean E. coli concentration less than or equal to 10/100 mL for lake/reservoir sources or 50/100 mL for flowing stream sources or do not exceed an alternative State-approved indicator trigger. PWSs that meet this criterion are classified in Bin 1 as shown in Table IV.B–1.

When determining the Cryptosporidium bin concentration, PWSs must calculate individual sample concentrations as the total number of oocysts counted, divided by the volume assayed (see section V.K for details). In samples where no oocysts are detected, the result is assigned a value of zero for the purpose of calculating the bin concentration. Sample analysis results are not adjusted for analytical method recovery or the percent of Cryptosporidium oocysts that are infectious.

PWSs must report their treatment bin classification to the State for approval following initial source water monitoring (see section IV.G for specific compliance dates). The report must include a summary of the data and calculation procedure used to determine the bin concentration. If EPA does not amend today's rule before the second round of monitoring described in section IV.A, PWSs must recalculate their bin classification after completing the second round of monitoring and report the results to the State for approval. If the State does not respond to a PWS regarding its bin classification after either report, the PWS must comply with the Cryptosporidium treatment requirements of today's rule based on the reported bin classification.

b. Bin treatment requirements. Table IV.B–2 shows the additional Cryptosporidium treatment requirements associated with the four treatment bins for filtered PWSs under today's rule. All filtered PWSs must comply with these treatment requirements based on their bin classification, which must be determined using the procedures just described.

TABLE IV.B–2.—TREATMENT REQUIREMENTS FOR LT2ESWTR BIN CLASSIFICATIONS

If your bin classification is . . .	And you use the following filtration treatment in full compliance with the SWTR, IESWTR, and LT1ESWTR (as applicable), then your additional treatment requirements are . . .		
	Conventional filtration treatment [1], diatomaceous earth filtration, or slow sand filtration	Direct filtration	Alternative filtration technologies
Bin 1	No additional treatment	No additional treatment	No additional treatment.
Bin 2	1-log treatment [2]	1.5-log treatment [2]	As determined by the State [2 4]
Bin 3	2-log treatment [3]	2.5-log treatment [3]	As determined by the State [3 5]
Bin 4	2.5-log treatment [3]	3-log treatment [3]	As determined by the State [3 6]

[1] Applies to a treatment train using separate, sequential, unit processes for coagulation/flocculation, clarification, and granular media filtration. Clarification includes any solid/liquid separation process following coagulation where accumulated solids are removed during this separate component of the treatment system.
[2] PWSs may use any technology or combination of technologies from the microbial toolbox in section IV.D.
[3] PWSs must achieve at least 1-log of the required treatment using ozone, chlorine dioxide, UV, membranes, bag filtration, cartridge filtration, or bank filtration.
[4] Total Cryptosporidium removal and inactivation must be at least 4.0 log.
[5] Total Cryptosporidium removal and inactivation must be at least 5.0 log.
[6] Total Cryptosporidium removal and inactivation must be at least 5.5 log.

The total Cryptosporidium treatment required for plants in Bins 2, 3, and 4 is 4.0-log, 5.0-log, and 5.5-log, respectively. Conventional treatment (including softening), slow sand, and diatomaceous earth filtration plants in compliance with the IESWTR or LT1ESWTR, as applicable, receive a prescribed 3.0-log Cryptosporidium treatment credit toward these total bin treatment requirements. Accordingly, these plant types must provide 1.0- to 2.5-log of additional treatment when classified in Bins 2–4, respectively. Direct filtration plants in compliance with existing regulations receive a prescribed 2.5-log treatment credit and, consequently, must achieve 0.5-log greater treatment to comply with Bins 2–4. Section IV.D describes how States may award a level of treatment credit that differs from the prescribed credit based on a demonstration of performance by the PWS.

For PWSs using alternative filtration technologies, such as membranes, bag filters, or cartridge filters, no prescribed treatment credit is available because the performance of these processes is specific to individual products. Consequently, when PWSs using these processes are classified in Bins 2–4, the State must determine additional treatment requirements based on the credit the State awards to a particular technology. The additional treatment requirements must ensure that plants classified in Bins 2–4 achieve total Cryptosporidium reductions of 4.0- to 5.5-log, respectively. Section IV.D describes challenge testing procedures to determine treatment credit for membranes, bag filters, and cartridge filters.

PWSs can achieve additional Cryptosporidium treatment credit through implementing pretreatment processes like presedimentation or bank filtration, by developing a watershed control program, and by applying additional treatment steps like ozone, chlorine dioxide, UV, and membranes. In addition, PWSs can receive a higher level of credit for existing treatment processes through achieving very low filter effluent turbidity or through a demonstration of performance. Section IV.D presents criteria for awarding Cryptosporidium treatment credit to these and other treatment and control options, which collectively comprise the microbial toolbox.

PWSs in Bin 2 can meet additional Cryptosporidium treatment requirements by using any option or combination of options from the microbial toolbox. For Bins 3 and 4, PWSs must achieve at least 1-log of the additional treatment requirement by using ozone, chlorine dioxide, UV, membranes, bag filtration, cartridge filtration, or bank filtration.

2. Background and Analysis

Today's rule will increase protection against Cryptosporidium and other pathogens in PWSs with the highest source water contamination levels. This targeted approach builds upon existing regulations under which all filtered PWSs must provide the same level of treatment regardless of source water quality. EPA's intent with today's rule is to ensure that PWSs with higher risk source waters achieve public health protection commensurate with PWSs with less contaminated sources.

The Cryptosporidium treatment requirements for filtered PWSs in today's rule are unchanged from the August 11, 2003 proposal (USEPA 2003a) and reflect consensus recommendations by the Stage 2 M–DBP Advisory Committee (USEPA 2000a). The following discussion summarizes the Agency's basis for establishing risk-targeted Cryptosporidium treatment requirements and for setting the specific bin concentration ranges and treatment requirements that apply to filtered PWSs in today's rule.

a. *Basis for targeted treatment requirements.* In developing today's rule, EPA evaluated the degree to which new information on Cryptosporidium warranted moving beyond existing regulations. As discussed in section III, the IESWTR established a Cryptosporidium MCLG of zero and requires large filtered PWSs to achieve 2-log Cryptosporidium removal. The LT1ESWTR extended this requirement to small PWSs. After these rules were promulgated, advances were made in analytical methods and treatment for Cryptosporidium, and EPA collected new information on Cryptosporidium occurrence and infectivity. Consequently, EPA assessed the implications of these developments for further controlling Cryptosporidium to approach the zero MCLG.

The risk-targeted approach for filtered PWSs in today's final rule stems from four general findings based on new information on Cryptosporidium:

(1) New data on Cryptosporidium infectivity suggest that the risk associated with a particular level of Cryptosporidium is most likely higher than EPA estimated at the time of earlier rules;

(2) New data on Cryptosporidium occurrence indicate that levels are relatively low in most water sources, but a subset of sources has substantially higher concentrations;

(3) The finding that UV light can readily inactivate Cryptosporidium, as well as other technology developments, makes achieving high levels of

treatment for Cryptosporidium feasible for PWSs of all sizes; and

(4) EPA Methods 1622 and 1623 are capable of assessing annual mean levels of Cryptosporidium in drinking water sources.

These findings led EPA to conclude that most filtered PWSs currently provide sufficient treatment for Cryptosporidium, but additional treatment is needed in those PWSs with the highest source water Cryptosporidium levels to protect public health. Further, PWSs can characterize Cryptosporidium levels in their source waters with available analytical methods and can provide higher levels of treatment with available technologies. Consequently, risk-targeted treatment requirements for Cryptosporidium based on source water contamination levels are appropriate and feasible to implement.

b. *Basis for bin concentration ranges and treatment requirements.* To establish the risk-targeted treatment requirements in today's rule, EPA had to determine the degree of treatment that should be required for different source water Cryptosporidium levels to protect public health. This determination involved addressing several questions:

- What is the risk associated with Cryptosporidium in a drinking water source?
- How much Cryptosporidium removal do filtration plants achieve?
- What is the appropriate statistical measure for classifying PWSs into treatment bins?
- What degree of additional treatment is needed for higher source water Cryptosporidium levels?
- How should PWSs calculate their treatment bin classification?

This section summarizes how EPA evaluated these questions in developing today's rule. See the proposed LT2ESWTR for further details (USEPA 2003a).

What is the Risk Associated With Cryptosporidium in a Drinking Water Source?

The risk of infection from Cryptosporidium in drinking water is a function of exposure (i.e., the dose of oocysts ingested) and infectivity (i.e., likelihood of infection as a function of ingested dose). Primary (i.e., direct) exposure to Cryptosporidium depends on the concentration of oocysts in the source water, the fraction removed by the treatment plant, and the volume of water consumed (secondary exposure occurs through interactions with infected individuals). Thus, the daily risk of infection (DR) is as follows:

$$DR = (\text{oocysts/L in source water}) \times (\text{fraction remaining after treatment}) \times (\text{liters consumed per day}) \times (\text{likelihood of infection per oocyst dose}).$$

Assuming 350 days of consumption per year for people served by community water systems (CWSs), the annual risk (AR) of infection is as follows:

$$AR = 1 - (1 - DR)^{350}.$$

As discussed in section III.E, EPA has estimated the mean likelihood of infection from ingesting one Cryptosporidium oocyst to range from 4 to 16 percent. Median individual daily water consumption is estimated as 1.07 L/day. Figure IV.B–1 illustrates ranges for the annual risk of infection by Cryptosporidium in CWSs based on these values for different source water infectious oocyst concentrations and treatment plant removal efficiencies. The dashed lines represent the uncertainty associated with Cryptosporidium infectivity for each log-removal curve. See Chapter 5 of the LT2ESWTR Economic Analysis for details (USEPA 2005a).

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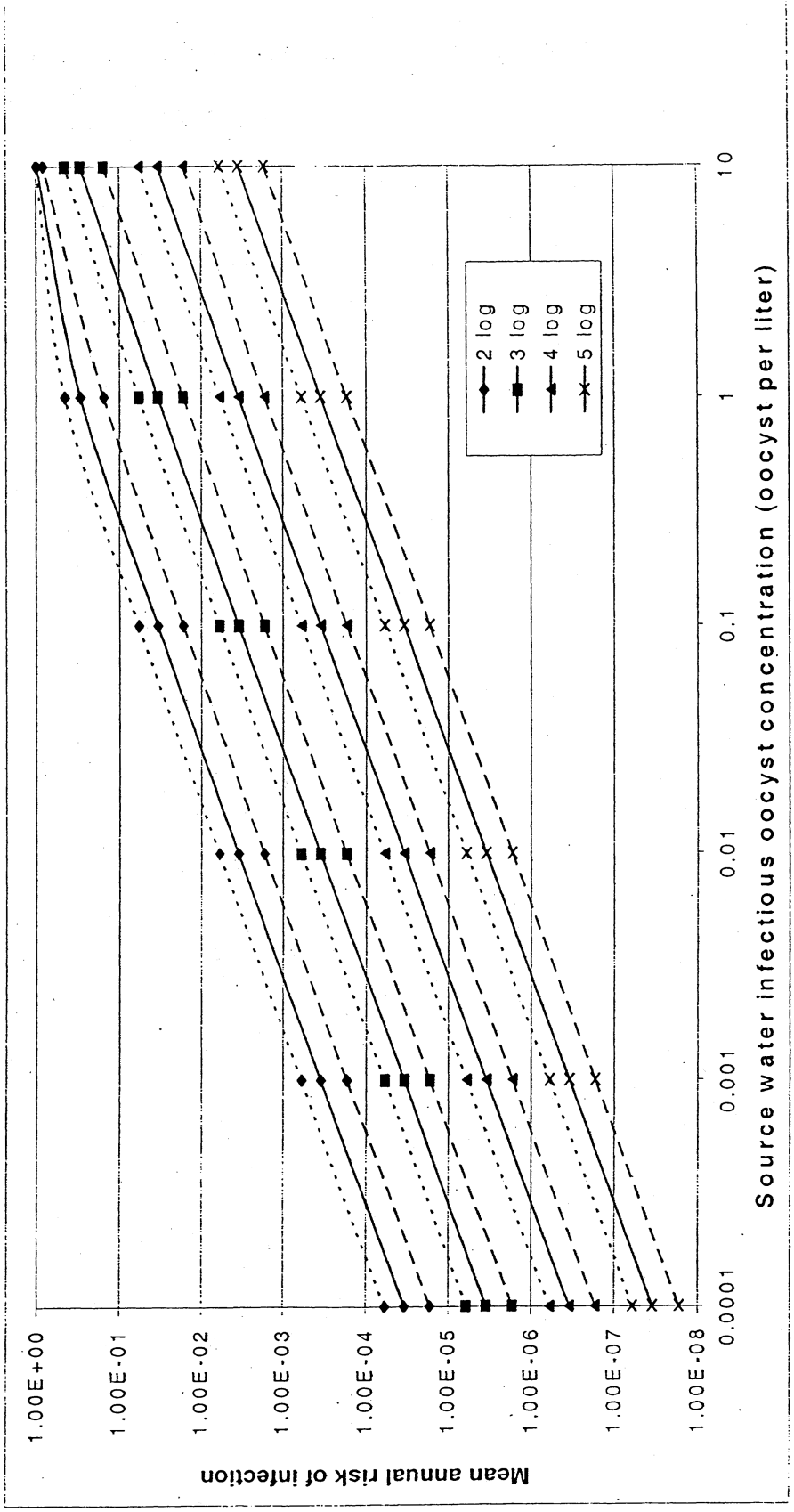

Figure IV.B-1.– Annual risk of *Cryptosporidium* infection as a function of source water infectious oocyst concentration for treatment plants achieving 2-log, 3-log, 4-log, or 5-log removal of oocysts.

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The results in Figure IV.B–1 show, for example, that if a treatment plant had a concentration of infectious Cryptosporidium in the source water of 0.1 oocysts/L and the plant achieved 3-log removal, the mean annual risk of

Cryptosporidium infection would range from 0.0017 to 0.0060 (17 to 60 infections per 10,000 consumers). In comparison, if the same plant had a source water infectious Cryptosporidium level of 0.01 oocysts/L, the annual infection risk would range from 1.7 to 6 per 10,000 consumers.

How much Cryptosporidium removal do filtration plants achieve?

The amount of Cryptosporidium removal that filtration plants achieve was a key factor in assessing the additional treatment that plants with higher source water Cryptosporidium levels should provide. To evaluate this factor, EPA reviewed studies of Cryptosporidium removal by common treatment processes. As described in the proposal for today's rule, these processes were conventional treatment, direct, slow sand, and diatomaceous earth filtration, as well as membrane, bag, and cartridge filtration (USEPA 2003a).

The majority of plants treating surface water use conventional treatment, which is defined in 40 CFR 141.2 as coagulation, flocculation, sedimentation, and filtration. In the proposal, EPA reviewed studies of conventional treatment by Dugan et al. (2001), Nieminski and Bellamy (2000), McTigue et al. (1998), Patania et al. (1999), Huck et al. (2000), Emelko et al. (2000), and Harrington et al. (2001). Based on these studies, EPA estimated that conventional treatment plants in compliance with the IESWTR or LT1ESWTR typically achieve a Cryptosporidium removal efficiency of approximately 3-log. Consequently, conventional treatment plants receive 3-log credit toward Cryptosporidium treatment requirements under today's rule.

This 3-log credit for conventional treatment is consistent with the Stage 2 M–DBP Agreement in Principle (USEPA 2000a), which states as follows:

''The additional treatment requirements in the bin requirement table are based, in part, on the assumption that conventional treatment plants in compliance with the IESWTR achieve an average of 3 logs removal of Cryptosporidium.''

The M–DBP Advisory Committee did not recommend a level of Cryptosporidium treatment credit for other types of filtration plants.

EPA also reviewed studies of the performance of clarification processes like dissolved air flotation, which can be used in place of sedimentation in a conventional treatment train (Gregory and Zabel 1990, Plummer et al. 1995, Edzwald and Kelley 1998). These studies indicate that plants using clarification processes other than sedimentation that are located after coagulation and prior to filtration can achieve performance equivalent to conventional treatment plants. As a result, any treatment train that includes coagulation/flocculation, clarification, and granular media filtration is regarded as conventional treatment for purposes of awarding treatment credit under today's rule. The clarification step must be a solid/liquid separation process where accumulated solids are removed during this separate component of the treatment system.

Direct filtration plants use coagulation, flocculation, and filtration processes just as conventional treatment plants do, but they lack a sedimentation basin or equivalent clarification process. In the proposal, EPA reviewed studies of sedimentation by Dugan et al. (2001), States et al. (1997), Edzwald and Kelly (1998), Payment and Franco (1993), Kelly et al. (1995), and Patania et al. (1995). Results from these studies demonstrate that sedimentation basins can achieve 0.5-log or greater Cryptosporidium removal. In addition, some studies have observed that direct filtration achieves less Cryptosporidium removal than conventional treatment (Patania et al. 1995) and the incidence of Cryptosporidium in the treated water is higher (McTigue et al. 1998). Given these findings, EPA has awarded direct filtration plants a 2.5-log credit towards Cryptosporidium treatment requirements under today's rule (i.e., 0.5-log less credit than for conventional treatment).

Slow sand filtration involves passing raw water through a bed of sand at low velocity and without prior coagulation. Diatomaceous earth filtration is a process by which a filtration medium is initially deposited onto a support membrane and medium is added throughout the operation to keep the filter from clogging. In the proposal, EPA reviewed slow sand filtration studies by Fogel et al. (1993), Hall et al. (1994), Schuler and Ghosh (1991), and Timms et al. (1995) and diatomaceous earth filtration studies by Schuler and Gosh (1990) and Ongerth and Hutton (1997, 2001). For both processes, these studies indicate that a well-designed and properly operated filter can achieve Cryptosporidium removal efficiencies similar to those observed for conventional treatment plants. Slow sand and diatomaceous earth filtration plants, therefore, receive a 3-log credit towards Cryptosporidium treatment requirements under today's rule.

Estimating a typical Cryptosporidium removal efficiency for filtration technologies like membranes, bag filters, and cartridge filters is not possible because the performance of such filters is specific to a particular product. As a result, credit for these devices must be determined by the State based on product-specific testing using the procedures described in section IV.D or other criteria approved by the State.

Table IV.B–3 summarizes the credits various types of filtration plants receive toward Cryptosporidium treatment requirements under today's rule. This credit determines the degree of additional treatment that plants classified in Bins 2–4 must apply, as shown in Table IV.B–2.

TABLE IV.B–3.—CRYPTOSPORIDIUM TREATMENT CREDIT TOWARDS LT2ESWTR REQUIREMENTS [1]

Plant type	Conventional treatment (includes softening)	Direct filtration	Slow sand or diatomaceous earth filtration	Alternative filtration technologies
Treatment credit	3.0-log	2.5-log	3.0-log	Determined by State. [2]

[1] Applies to plants in full compliance with the IESWTR or LT1ESWTR as applicable.
[2] Credit must be determined through product or site-specific assessment.

As discussed previously, studies indicate that conventional treatment plants producing very low filtered water turbidity can achieve a higher level of Cryptosporidium removal than 3-log, and today's rule allows such plants to receive additional treatment credit. Further, States can award a higher or lower level of credit to an individual plant based on a site-specific demonstration of performance. Section IV.D provides details on both of these topics.

The Cryptosporidium removal credits for filtration plants in today's rule differ from the amount of credit awarded under the IESWTR and LT1ESWTR. As

discussed in section III, those rules require all filtered PWSs to achieve 2-log removal of Cryptosporidium. PWSs using conventional treatment, or direct, slow sand, or diatomaceous earth filtration are in compliance with this requirement if they meet specified filtered water turbidity standards. These regulatory criteria were based on consideration of the minimum level of removal that all these filtration processes will achieve (USEPA 1998a). However, in the risk assessments that supported these regulations, EPA estimated that most filtration plants will achieve significantly more removal, with median Cryptosporidium reductions near 3-log.

Today's rule will supplement IESWTR and LT1ESWTR requirements by mandating additional treatment at certain PWSs based on source-water Cryptosporidium levels. When assessing the need for additional treatment at potentially higher risk PWSs, EPA believes that considering the full removal efficiency achieved by different types of treatment plants is appropriate. Because making a site-specific assessment of removal efficiency at all treatment plants individually is not feasible, establishing prescribed treatment credits based on available data is necessary. Accordingly, EPA has concluded that available data support the higher levels of prescribed credit towards Cryptosporidium treatment requirements for filtration plants established by today's rule.

What is the appropriate statistical measure for classifying PWSs into treatment bins?

EPA and the Advisory Committee evaluated different statistical measures for characterizing Cryptosporidium monitoring results to determine if additional treatment should be required. These measures included the arithmetic mean, median, 90th percentile, and maximum.

EPA concluded, consistent with Advisory Committee recommendations, that Cryptosporidium levels should be characterized by an arithmetic mean. This conclusion is based on two factors: (1) Available data suggest that the mean concentration directly relates to the average risk of the exposed population (i.e., drinking water consumers); and (2) with a limited number of samples, the mean can be estimated more accurately than other statistical measures, such as a 90th percentile estimate.

What degree of additional treatment is needed for higher source water Cryptosporidium levels?

Development of the risk-based treatment requirements in today's rule involved first determining the threshold source-water Cryptosporidium level at which filtered PWSs should provide additional treatment to protect public health. The key factors in making this determination were the estimations of Cryptosporidium risk and treatment plant removal efficiency discussed previously, along with the performance of analytical methods for classifying PWSs in different treatment bins.

EPA and Advisory Committee deliberations focused on mean source-water Cryptosporidium concentrations in the range of 0.01 to 0.1 oocysts/L as threshold levels for requiring additional treatment. Based on the type of risk information shown in Figure IV.B–1, these levels are estimated to result in an annual infection risk in the range of 1.7×10^{-4} to 6.0×10^{-3} (or 1.7 to 60 infections per 10,000 consumers) for a treatment plant achieving 3-log Cryptosporidium removal (the treatment efficiency estimated for conventional plants under existing regulations).

A shortcoming with establishing the threshold for additional treatment at 0.01 oocysts/L, however, is that a PWS would exceed this concentration with only a very few oocysts being detected. For a PWS collecting monthly 10-L samples and bin classification based on the maximum running annual average, as required under today's rule, detecting two oocysts during one year of monitoring would exceed a mean of 0.01 oocysts/L. Given the uncertainty associated with Cryptosporidium monitoring, EPA and the Advisory Committee did not support requiring additional treatment for filtered PWSs based on so few counts. Although this shortcoming could theoretically be addressed by a higher sampling frequency, the feasibility of increased sampling is limited by the capacity of laboratories and the cost of sample analysis.

A related concern in establishing the threshold concentration for requiring additional treatment was bin misclassification. If the threshold concentration was set at 0.1 oocysts/L, for example, some PWSs with actual mean source-water concentrations greater than this level would measure a concentration less than this level and would be misclassified in the bin that requires no additional treatment. Consequently, they would not provide sufficient public health protection. As discussed previously, this type of error is due to the limited number and volume of samples that can be analyzed, imperfect method recovery, and variability in Cryptosporidium occurrence.

Based on these considerations, the Advisory Committee recommended and today's rule establishes that filtered PWSs must provide additional treatment for Cryptosporidium when their mean source-water concentration exceeds 0.075 oocysts/L. At this concentration, PWSs collecting monthly 10-L samples must count at least nine oocysts in one year (9 oocysts per 120 L total sample volume) before additional treatment is required. Further, any PWS with a mean source-water infectious Cryptosporidium level above 0.1 oocysts/L, which corresponds to an estimated infection risk range of 1.7 to 6.0×10^{-3}, is highly likely to be appropriately classified in a bin requiring additional treatment.

After identifying this first threshold for requiring additional treatment, determining the Cryptosporidium concentrations that should bound higher treatment bins was necessary. In making these determinations, EPA concurred with Advisory Committee recommendations that sought to balance the possibility of bin misclassification against equitable risk reduction and public health protection.

Treatment bins that span a wider concentration range result in lower bin misclassification rates. The analysis summarized in section IV.A shows that the monitoring required under today's rule can accurately characterize a PWS's mean Cryptosporidium level within a 0.5-log margin, but error rates increase for smaller margins (USEPA 2005a). Conversely, treatment bins that span a narrower concentration range provide more equitable protection from risk among different PWSs. This is due to identical treatment requirements applying to all PWSs in the same bin. In consideration of these issues, today's rule establishes two higher treatment bins at Cryptosporidium concentrations of 1.0 oocysts/L and 3.0 oocysts/L. These values result in the four bins shown in Table IV.B–1. Available occurrence data indicate that few PWSs will measure mean Cryptosporidium concentrations greater than 3.0 oocysts/L, so there is no need to establish a treatment bin above this level.

With respect to the degree of additional Cryptosporidium treatment that PWSs in Bins 2–4 must provide, EPA and the Advisory Committee considered values of 0.5-log and greater. Today's rule establishes a 1-log additional treatment requirement for conventional plants in Bin 2. Because

the concentration range of Bin 2 spans approximately one order of magnitude, this degree of treatment ensures that plants classified in Bin 2 will achieve treated water Cryptosporidium levels comparable to plants in Bin 1. Conventional plants in Bins 3 and 4 must provide 2.0- and 2.5-log of additional treatment, respectively. As recommended by the Advisory Committee, these higher additional treatment levels are required based on the recognition that plants in Bins 3 and 4 have a much greater potential vulnerability to Cryptosporidium. Consequently, significantly higher treatment is appropriate to protect public health.

These additional treatment requirements for conventional treatment plants in Bins 2–4 are based on a prescribed 3-log Cryptosporidium treatment credit for compliance with the IESWTR or LT1ESWTR, as discussed previously. They translate to total Cryptosporidium treatment requirements of 4.0-, 5.0-, and 5.5-log for Bins 2, 3, and 4, respectively. Plants receiving higher or lower levels of prescribed treatment credit are required to provide less or more additional treatment if classified in Bins 2–4.

Plants using slow sand or diatomaceous earth filtration, which also receive a 3-log treatment credit, incur the same additional treatment requirements as conventional plants if classified in Bins 2–4. Direct filtration plants, however, must provide 0.5-log greater additional treatment if classified in Bins 2–4 because they receive a 2.5-log prescribed credit. EPA expects, though, that most direct filtration plants will be classified in Bin 1 because direct filtration is typically applied only to higher quality source waters.

Because EPA is unable to establish a prescribed treatment credit for other types of filtration technologies like membranes, bag filters, and cartridge filters, today's rule requires that States assign a treatment credit to a particular filtration product. This credit then determines the amount of additional treatment that a plant using this product must provide if classified in Bins 2–4 in order to achieve the required total treatment level. Section IV.D provides criteria for assigning Cryptosporidium treatment credit to membranes, bag filters, and cartridge filters.

As described in Section IV.D, today's rule establishes a wide range of treatment and control options through the microbial toolbox for PWSs to meet additional Cryptosporidium treatment requirements. PWSs may choose any option or combination of options from the microbial toolbox to meet the treatment requirements of plants in Bin 2. For plants in Bins 3 or 4, though, PWSs must achieve at least 1-log of the additional treatment requirement using UV, ozone, chlorine dioxide, membranes, bag filters, cartridge filters, or bank filtration. EPA is establishing this provision in today's rule as recommended by the Advisory Committee because these processes will serve as significant additional treatment barriers for PWSs with the highest levels of pathogens in their sources.

How should PWSs calculate their treatment bin classification?

The specific calculations that PWSs use to determine their bin classification are based on analyses of misclassification rates and bias. As described in section IV.A, today's rule requires PWSs to collect at least 24 samples (except for plants that operate only part-year) when they monitor for Cryptosporidium. Most PWSs will collect these 24 samples over two years, but PWSs may sample at a higher frequency and small PWSs may complete this monitoring in one year. These differences affect the bin classification calculation.

PWSs that sample monthly over two years (24 samples total) must use the maximum running annual average (Max-RAA) for bin classification because this achieves a low false negative rate (the likelihood a PWS will be incorrectly classified in a lower bin). In comparison, if such PWSs used the mean of all samples over two years for bin classification, the false negative rate would be almost four times higher (see Table IV.B.4).

PWSs that choose to sample at least twice per month over two years (48 samples total) must use the mean of all 48 samples for their bin classification. This approach achieves a low false negative rate similar to the Max-RAA for 24 samples and, in addition, reduces the false positive rate (the likelihood a PWS will be incorrectly classified in higher bin—see Table IV.B.4). Due to the lower false positive rate associated with 48 samples, EPA expects that some PWSs will choose to sample for Cryptosporidium twice per month.

Small PWSs (serving fewer than 10,000 people) that complete their Cryptosporidium monitoring over one year must use the mean of all 24 samples for bin classification. This approach has a higher false negative rate than the approaches allowed for PWSs that monitor over two years. However, it is the only feasible option for PWSs that conduct just one year of Cryptosporidium sampling. Averaging sample concentrations over less than one year is not appropriate (except in the case of plants that operate only part-year that monitor for less than one year) as this would bias the bin classification due to seasonal variation in water quality.

TABLE IV.B–4.—FALSE POSITIVE AND FALSE NEGATIVE RATES FOR MONITORING AND BINNING STRATEGIES CONSIDERED FOR THE LT2ESWTR

Strategy	False positive [1]	False negative [2]
48 sample arithmetic mean ...	1.7%	1.4%
24 sample Max-RAA	5.3%	1.7%
24 sample arithmetic mean ...	2.8%	6.2%

[1] False positive rates calculated for systems with Cryptosporidium concentrations 0.5 log below the Bin 1 boundary of 0.075 oocysts/L.

[2] False negative rates calculated for systems with Cryptosporidium concentrations 0.5 log above the Bin 1 boundary of 0.075 oocysts/L.

Two additional considerations that relate to characterizing Cryptosporidium monitoring results to determine treatment requirements are (1) fewer than 100 percent of oocysts in a sample are recovered and counted by the analyst and (2) not all the oocysts measured with Methods 1622 or 1623 are capable of causing infection. These two factors are offsetting, in that oocyst counts not adjusted for recovery tend to underestimate the true concentration, while the total oocyst count typically overestimates the infectious concentration that presents a health risk.

As described in section III, matrix spike data indicate that average recovery of Cryptosporidium oocysts with Methods 1622 or 1623 in a national monitoring program will be approximately 40 percent. Regarding the fraction of oocysts that are infectious, LeChevallier et al. (2003) tested natural waters for Cryptosporidium using both Method 1623 and a method (cell culture-PCR) to test for infectivity. Results suggested that 37 percent of the Cryptosporidium oocysts detected by Method 1623 were infectious. This finding is consistent with the observation that 37 percent of the oocysts counted during the ICRSS using Methods 1622 or 1623 had internal structures, which indicate a higher likelihood of infectivity (among the remaining oocysts, 47 percent had amorphous structures and 16 percent were empty).

While it is not possible to establish a precise value for method recovery or the fraction of oocysts that are infectious,

available data suggest that these parameters may be of similar magnitude. Consequently, the Advisory Committee recommended that monitoring results should not be adjusted to account for either recovery or the fraction infectious. EPA concurs with this recommendation and today's rule requires that PWSs be classified in treatment bins using the total number of Cryptosporidium oocysts counted, without further adjustment. The LT2ESWTR treatment bins in today's rule are constructed to reflect this approach.

3. Summary of Major Comments

For filtered PWS treatment requirements in the LT2ESWTR proposal, EPA received significant public comment on the risk-based approach to requiring additional treatment, the role of States in determining bin classification, and the treatment credit for filtration plants. The following discussion summarizes comments in these areas and EPA's responses.

Most commenters supported the risk-based approach of the LT2ESWTR in which filtered PWSs monitor for microbial contaminants and only those PWSs finding higher levels of contamination are required to provide additional treatment for Cryptosporidium. Among these comments, many stated support for the four treatment bins for filtered PWSs, with some noting that future research will indicate whether the bins should be restructured in a later rulemaking. Several commenters expressed support for EPA's combination of the Stage 2 DBPR and LT2ESWTR as essential to creating a balanced approach between DBP control and microbial risk.

A few commenters opposed the expenditure of funds to reduce risk from Cryptosporidium on the basis that epidemiological evidence suggests this risk is low and most communities have not experienced cryptosporidiosis outbreaks. EPA agrees that additional treatment for Cryptosporidium in drinking water is not warranted in all communities. Under today's rule, most PWSs are expected to be classified in the lowest bin, which requires no additional treatment. However, based on risk information presented in USEPA (2005a) and summarized in this preamble, EPA believes that additional treatment is necessary to protect public health in PWSs with the highest Cryptosporidium levels. Further, as described in USEPA (2005a), EPA's assessment of Cryptosporidium risk in drinking water is consistent with the limited available epidemiological data on disease incidence.

With respect to the role of States in bin classification, most commenters recommended that States assign or approve the bin classification for their PWSs. Commenters maintained that State approval of bin classification is an inherent governmental function and will avoid confusion as to the level of treatment each PWS must provide. Further, the approval process will provide an opportunity for dialog between States and PWSs. EPA agrees with these comments and today's rule requires PWSs to submit their calculation of bin classification to the State for review. If the PWS does not hear back from the State, it must proceed to apply the level of treatment appropriate for its calculated bin classification in accordance with its applicable compliance schedule.

In regard to the Cryptosporidium treatment credit that should be awarded to filtration plants, many commenters supported the 3-log Cryptosporidium removal credit for conventional treatment and slow sand filtration. Some comments included data showing that conventional treatment can achieve greater than 4-log removal of Cryptosporidium, and several commenters stated concerns that EPA has underestimated the level of treatment achievable through conventional treatment. Commenters supported the inclusion of plants using softening and dissolved air flotation for conventional treatment credit and requested that EPA extend this credit to similar treatment trains using other types of clarification processes.

EPA recognizes that studies show conventional treatment can achieve more than 3-log Cryptosporidium removal under optimal conditions. However, studies also demonstrate that removal efficiencies can be significantly less for suboptimal plant set-up and operation. EPA does not expect that all plants will operate under optimal conditions at all times. Consequently, today's rule awards a prescribed 3-log credit to conventional plants complying with the IESWTR or LT1ESWTR and allows plants to receive higher credit through demonstrating low finished water turbidity or through an alternative demonstration of performance, as describe in section IV.D. EPA agrees that plants using alternative clarification process that involves solids removal between coagulation and filtration should qualify for 3-log credit and today's rule provides for this.

C. Unfiltered System Cryptosporidium Treatment Requirements

1. Today's Rule

Today's rule requires all PWSs that use a surface water or GWUDI source and are unfiltered to provide treatment for Cryptosporidium. The degree of required treatment depends on the level of Cryptosporidium in the source water, as determined through required monitoring. Further, unfiltered PWSs must meet overall treatment requirements using at least two disinfectants and must continue to meet all applicable filtration avoidance criteria. Details of these requirements follow.

a. *Determination of mean Cryptosporidium level.* Following completion of the required initial source water monitoring described in section IV.A, each unfiltered PWS must determine the arithmetic mean of all its Cryptosporidium sample results generated during the monitoring period. As required for filtered PWSs, individual sample results must be calculated as the total number of oocysts counted, divided by the volume assayed (see section V.K for details). Samples are not adjusted for method recovery and, in samples where no oocysts are detected, the result is treated as zero.

Unfiltered PWSs must report their mean Cryptosporidium level to the State for approval (see section IV.G for specific reporting dates). The report must include a summary of the data used to determine the mean concentration. If the State does not respond to a PWS regarding its mean Cryptosporidium level, the PWS must comply with the Cryptosporidium treatment requirements of today's rule, as described next, based on the reported level.

If EPA does not amend today's rule before the second round of monitoring described in section IV.A, unfiltered PWSs must recalculate their mean Cryptosporidium level using results from the second round of monitoring. Unfiltered PWSs must report this level to the State as described for the initial round of monitoring.

b. *Cryptosporidium treatment requirements.* Unfiltered PWSs must comply with the following treatment requirements based on their mean source-water Cryptosporidium level: if the level is less than or equal to 0.01 oocysts/L then at least 2-log Cryptosporidium inactivation is required; if the level is greater than 0.01 oocysts/L, or if the unfiltered PWS chooses not to monitor for Cryptosporidium, then at least 3-log Cryptosporidium inactivation is

required. See section IV.G for treatment compliance dates.

EPA has developed criteria, described in section IV.D, to award Cryptosporidium inactivation credit for treatment with chlorine dioxide, ozone, or UV light. Unfiltered PWSs may use any of these disinfectants to meet their Cryptosporidium inactivation requirements under today's rule. Further, unfiltered PWSs must achieve the following with respect to disinfection treatment:

(1) A PWS that uses chlorine dioxide or ozone and fails to achieve the required level of Cryptosporidium inactivation on more than one day in the calendar month is in violation of the treatment technique requirement.

(2) A PWS that uses UV light and fails to achieve the required level of Cryptosporidium inactivation in at least 95 percent of the water delivered to the public every month is in violation of the treatment technique requirement.

c. *Use of two disinfectants.* Unfiltered PWSs must use at least two different disinfectants to provide 4-log virus, 3-log Giardia lamblia, and 2- or 3-log Cryptosporidium inactivation as required under 40 CFR 141.72(a) and today's rule. Further, each of two disinfectants must achieve by itself the total inactivation required for one of these target pathogens. This requirement does not modify the existing requirement under 40 CFR 141.72(a) for PWSs to provide a disinfectant residual in the distribution system.

2. Background and Analysis

The intent of the Cryptosporidium treatment requirements for unfiltered PWSs in today's final rule is to ensure that they achieve public health protection equivalent to that achieved by filtered PWSs. These requirements are unchanged from the August 11, 2003 proposal (USEPA 2003a), and they reflect consensus recommendations by the Stage 2 M–DBP Advisory Committee (USEPA 2000a). The following discussion summarizes the Agency's basis for establishing risk-targeted Cryptosporidium treatment requirements for unfiltered PWSs in today's rule and for requiring the use of two disinfectants.

a. *Basis for Cryptosporidium treatment requirements.* As described in section III, available data suggest that unfiltered PWSs must take additional steps to achieve public health protection against Cryptosporidium equivalent to that provided by filtered PWSs.

In occurrence data from the ICR, the median Cryptosporidium level in unfiltered PWS sources was 0.0079 oocysts/L, which is approximately 10 times less than the median level of 0.052 oocysts/L in filtered PWS sources. In translating these source water levels to finished water concentrations, EPA and the Advisory Committee assumed that conventional filtration treatment plants in compliance with the IESWTR or LT1ESWTR achieve an average of 3-log (99.9 percent) removal of Cryptosporidium. Existing regulations do not require unfiltered PWSs to provide any treatment for Cryptosporidium.

If the median source water Cryptosporidium level in filtered PWSs is approximately 10 times higher than in unfiltered PWSs, and filtered PWSs achieve 3-log Cryptosporidium removal, then the median finished water Cryptosporidium level in filtered PWSs is approximately 100 times lower than in unfiltered PWSs. Thus, these data suggest that most unfiltered PWSs must provide 2-log Cryptosporidium treatment to ensure equivalent public health protection.

Some unfiltered PWSs must provide greater than 2-log Cryptosporidium treatment to ensure equitable protection, depending on their source water level. Under today's rule, the Cryptosporidium treatment requirements for filtered PWSs, as described in section IV.B.1, will achieve mean finished water Cryptosporidium levels of less than 1 oocyst/10,000 L. An unfiltered PWS with a mean source water Cryptosporidium concentration above 0.01 oocysts/L would have to provide at least 3-log inactivation to achieve an equivalent finished water Cryptosporidium level.

As stated earlier, EPA has determined that UV light is a feasible technology for PWSs of all sizes, including unfiltered PWSs, to inactivate Cryptosporidium. In addition, treating for Cryptosporidium using ozone is feasible for some unfiltered PWSs. Inactivating Cryptosporidium with chlorine dioxide, while allowed under today's rule, does not appear to be feasible for most unfiltered PWSs due to regulatory limits on chlorite—a chlorine dioxide byproduct.

Based on these findings, today's rule requires all unfiltered PWSs to provide at least 2-log Cryptosporidium inactivation, and to provide at least 3-log inactivation if the mean source water level exceeds 0.01 oocysts/L. These treatment requirements will ensure that unfiltered PWSs achieve public health protection against Cryptosporidium that is comparable to filtered PWSs in the finished water that is distributed to consumers.

Available data indicate that no unfiltered PWSs will show measured mean source water Cryptosporidium levels of 0.075 oocysts/L or higher—the level at which a filtered PWS must provide at least 4-log Cryptosporidium under today's rule. Consequently, EPA is not establishing treatment requirements in today's rule to address Cryptosporidium at this higher level. Under existing regulations (40 CFR 141.171 and 141.521), unfiltered PWSs must maintain a watershed control program that minimizes the potential for contamination by Cryptosporidium oocysts in the source water. If the measured mean Cryptosporidium level in an unfiltered PWS is 0.075 oocysts/L or higher, EPA believes the State should critically evaluate the adequacy of the watershed control program.

Under today's rule, unfiltered PWSs using ozone or chlorine dioxide to treat for Cryptosporidium must demonstrate the required 2- or 3-log inactivation every day the PWS serves water to the public, except any one day each month. Existing regulations (40 CFR 141.72(a)(1)) require unfiltered PWSs to ensure inactivation of 3-log Giardia lamblia and 4-log viruses every day except any one day per month. Consequently, today's rule extends this compliance standard to Cryptosporidium inactivation.

For unfiltered PWSs that use UV to treat for Cryptosporidium, today's rule requires demonstration of the required 2- or 3-log inactivation in at least 95 percent of the water delivered to the public every month. EPA intends this standard to be comparable to the ''every day except any one day per month'' standard established for ozone and chlorine dioxide. Because UV disinfection systems will typically consist of multiple reactors that will be monitored continuously, EPA believes that a compliance standard based on the percentage of water disinfected to the required level is more appropriate than a single daily measurement. Section IV.D describes an equivalent standard for filtered PWSs.

b. *Basis for requiring the use of two disinfectants.* Unfiltered PWSs must use at least two different disinfectants to meet the inactivation requirements for Cryptosporidium (2- or 3-log), Giardia lamblia (3-log) and viruses (4-log), and each of two disinfectants must achieve by itself the total inactivation required for one of these target pathogens. For example, a PWS could use UV light to achieve 3-log inactivation of Giardia lamblia and Cryptosporidium and use chlorine to provide 4-log virus inactivation. The use of two disinfectants protects public health by creating multiple barriers against microbial pathogens. This has two

general advantages over a single barrier: improved reliability and a broader spectrum of efficacy.

Because unfiltered PWSs rely solely on inactivation for microbial treatment, an unfiltered PWS using only one disinfectant would provide no primary microbial treatment if that disinfection process were to fail. While disinfection processes should be designed for a high level of reliability, they are not generally 100 percent reliable. Existing regulations and today's rule recognize this limitation by allowing unfiltered PWSs to fail to achieve required disinfection levels one day per month. Consequently, EPA believes that for effective public health protection, unfiltered PWSs should use at least two primary disinfection processes. If one process fails, a second process will provide some degree of protection against pathogens.

A second advantage of a PWS using multiple disinfectants is that this approach will typically be more effective against a broad spectrum of pathogens. The efficacy of different disinfectants against different types of pathogens varies widely. For example, UV light appears to be very effective for inactivating protozoa like Cryptosporidium and Giardia lamblia, but is less effective against certain enteric viruses like adenovirus. Chlorine, however, is highly effective against enteric viruses but less effective against protozoa. As a result, multiple disinfectants will generally provide more effective inactivation of a wide range of pathogens than a single disinfectant.

c. *Filtration avoidance.* Today's rule does not withdraw or modify any existing criteria for avoiding filtration under 40 CFR 141.71. Accordingly, unfiltered PWSs must continue to comply with all existing filtration avoidance criteria. EPA believes these criteria help to ensure that watershed protection provides a microbial barrier in those PWSs that do not filter.

Further, today's rule does not establish any new criteria for filtration avoidance. In the proposed LT2ESWTR, EPA indicated that compliance with DBP standards under the Stage 2 DBPR would be incorporated into the criteria for filtration avoidance. However, EPA has not done this in today's final rule in order to give States more flexibility in working with unfiltered PWSs to comply with the Stage 2 DBPR.

3. Summary of Major Comments

EPA received significant public comment on the following treatment requirements for unfiltered PWSs in the LT2ESWTR proposal: the requirement for all unfiltered PWSs to provide at least 2-log Cryptosporidium inactivation, treatment requirements for unfiltered PWSs with high Cryptosporidium levels, and the requirement for unfiltered PWSs to use at least two disinfectants. A summary of these comments and EPA's responses follows.

Several commenters supported the requirement that all unfiltered PWSs achieve at least 2-log inactivation of Cryptosporidium, noting that this was part of the Agreement in Principle (USEPA 2000a). Some commenters, however, requested that EPA not establish a minimum Cryptosporidium treatment level due to the following factors: monitoring of unfiltered PWS sources has shown very low levels of Cryptosporidium, and some sources may have no Cryptosporidium; the Cryptosporidium in an unfiltered PWS source are likely to be of non-human origin and are less likely to infect humans; and disease incidence data have not established a link between unfiltered PWSs and cryptosporidiosis in consumers.

In response, EPA continues to believe that all unfiltered PWSs should provide treatment for Cryptosporidium to protect public health. Monitoring has shown that unfiltered PWS sources are contaminated with Cryptosporidium, and no source is likely to be entirely free of Cryptosporidium due to the ubiquity of Cryptosporidium in both human and many animal populations. Studies, such as those cited in section III, have established that Cryptosporidium from animals can infect humans. EPA does not regard the absence of cryptosporidiosis cases attributed to drinking water in a particular community as evidence that no treatment for Cryptosporidium is needed. As described in section III, cryptosporidiosis incidence data generally do not indicate overall disease burden because most cases are undetected, unreported, and not traced to a particular source.

Some commenters recommended that EPA require only 1-log Cryptosporidium inactivation for unfiltered PWSs that demonstrate source water levels below 0.001 oocysts/L. EPA does not support this approach, though, due to concerns with the reliability of monitoring to establish such an extremely low level of Cryptosporidium. In addition, UV light is a feasible technology for unfiltered PWSs of all sizes to achieve at least 2-log Cryptosporidium inactivation. For these reasons, EPA has concluded that the minimum Cryptosporidium treatment level should be 2-log, as recommended by the Advisory Committee.

In the proposed LT2ESWTR, EPA requested comment on the treatment that should be required if an unfiltered PWS measured a Cryptosporidium level of 0.075 oocysts/L or higher—the concentration at which a filtered PWS must provide at least 4-log treatment. Several commenters supported equivalent treatment requirements (i.e., at least 4-log reduction) for unfiltered and filtered PWSs with Cryptosporidium at this level. Other commenters stated that available data indicate no unfiltered PWSs are likely to measure Cryptosporidium at such a high level.

EPA agrees that available data on Cryptosporidium occurrence suggest that no unfiltered PWSs will measure a mean level of 0.075 oocysts/L or higher. Moreover, establishing a 4-log treatment requirement on the precautionary basis that an unfiltered PWS might measure a high level of Cryptosporidium has a significant cost—it would require any unfiltered PWS to provide 4-log, rather than 3-log, inactivation to avoid Cryptosporidium monitoring. EPA expects that many small unfiltered PWSs will choose to provide 3-log Cryptosporidium inactivation rather than monitor for Cryptosporidium. Accordingly, EPA has concluded that establishing a 4-log Cryptosporidium treatment requirement for unfiltered PWSs that measure a Cryptosporidium level of 0.075 oocysts/L or higher is unnecessary and inappropriate at this time. In the event that an unfiltered PWS does measure Cryptosporidium at this level, the State can require the PWS to take steps to reduce the contamination under existing watershed control program requirements for unfiltered PWSs.

Some commenters supported the requirement for unfiltered PWSs to use at least two disinfectants to meet overall inactivation requirements for Cryptosporidium, Giardia lamblia, and viruses and for each disinfectant to achieve the total inactivation required for one target pathogen. These commenters stated that this requirement will improve inactivation against a wide variety of pathogens and increase treatment reliability. Other commenters, though, opposed this requirement for a number of reasons: it will unnecessarily limit the ability of PWSs to minimize DBPs, there is no similar requirement for filtered PWSs, the requirement for each disinfectant to achieve the total inactivation for one pathogen goes beyond the Agreement in Principle, and EPA has not provided a risk analysis to justify the requirement.

In response, EPA believes that the benefits of both redundancy and a broad spectrum of microbial protection justify requiring the use of two disinfectants. Further, requiring each disinfectant to achieve the full inactivation of one target pathogen establishes a minimal performance level so that each disinfectant will serve as a substantive barrier. In most cases, PWSs will comply with this requirement by using UV or ozone to inactivate Giardia lamblia and Cryptosporidium and using chlorine to inactivate viruses.

D. Options for Systems To Meet Cryptosporidium Treatment Requirements

1. Microbial Toolbox Overview

Today's rule includes a variety of treatment and control options, collectively termed the ''microbial toolbox,'' that PWSs can implement to comply with additional Cryptosporidium treatment requirements. Options in the microbial toolbox include source protection and management programs, prefiltration processes, treatment performance programs, additional filtration components, and inactivation technologies. The Stage 2 M–DBP Advisory Committee recommended the microbial toolbox to provide PWSs with broad flexibility in selecting cost-effective LT2ESWTR compliance strategies.

Most options in the microbial toolbox carry prescribed credits toward Cryptosporidium treatment requirements. PWSs receive these credits by demonstrating compliance with required design and operational criteria, which are described in the sections that follow. In addition, States may award treatment credits other than the prescribed credit through a ''demonstration of performance,'' which involves site-specific testing by a PWS with a State-approved protocol. Under a demonstration of performance, a State may award credit to a treatment plant or to a unit process of a treatment plant that is higher or lower than the prescribed credit. This option also allows States to award credit to a unit process that does not meet the design and operational criteria in the microbial toolbox for prescribed credit.

To be eligible for treatment credit for a microbial toolbox option, PWSs must initially report compliance with design criteria, where required, to the State (some options do not require design criteria). Thereafter, for most options, PWSs must report compliance with required operational criteria to the State each month (the watershed control program option requires yearly reporting). Failure by a PWS in any month to demonstrate treatment credit equal to or greater than its Cryptosporidium treatment requirements under today's rule is a treatment technique violation. This violation lasts until the PWS demonstrates that it is meeting criteria for sufficient treatment credit to satisfy its Cryptosporidium treatment requirements.

As described in section IV.B, filtered PWSs may use any option or combination of options from the microbial toolbox to comply with the additional Cryptosporidium treatment requirements of Bin 2. PWSs in Bins 3 or 4 must achieve at least 1-log of the additional Cryptosporidium treatment requirement by using ozone, chlorine dioxide, UV, membranes, bag filtration, cartridge filtration, or bank filtration.

If allowed by the State, PWSs may use different microbial toolbox options in different months to comply with Cryptosporidium treatment requirements under today's rule. For example, a PWS in Bin 2, which requires 1-log additional Cryptosporidium treatment, could comply with this requirement in one month using ''individual filter performance,'' which carries a 1-log credit; in a subsequent month, this PWS could use ''combined filter performance'' and ''presedimentation basin with coagulation,'' which each carry 0.5-log credit. This approach is intended to provide greater operational flexibility to PWSs. It allows a PWS to receive treatment credit for a microbial toolbox option in any month the PWS is able to meet required operational criteria, even if the PWS does not meet these criteria during all months of the year.

Table IV.D–1 summarizes prescribed treatment credits and associated design and operational criteria for microbial toolbox options. The sections that follow describe each toolbox option in detail. In addition, EPA has developed three guidance documents to assist PWSs with selecting and implementing microbial toolbox options: Toolbox Guidance Manual, UV Disinfection Guidance Manual, and Membrane Filtration Guidance Manual. Each may be acquired from EPA's Safe Drinking Water Hotline, which can be contacted as described under **FOR FURTHER INFORMATION CONTACT** at the beginning of this notice.

TABLE IV.D–1.—MICROBIAL TOOLBOX: OPTIONS, CREDITS AND CRITERIA

Toolbox option	Cryptosporidium treatment credit with design and operational criteria [1]
Source Protection and Management Toolbox Options	
Watershed control program	0.5-log credit for State-approved program comprising required elements, annual program status report to State, and regular watershed survey. Unfiltered PWSs are not eligible for credit.
Alternative source/intake management.	No prescribed credit. PWSs may conduct simultaneous monitoring for treatment bin classification at alternative intake locations or under alternative intake management strategies.
Prefiltration Toolbox Options	
Presedimentation basin with coagulation.	0.5-log credit during any month that presedimentation basins achieve a monthly mean reduction of 0.5-log or greater in turbidity or alternative State-approved performance criteria. To be eligible, basins must be operated continuously with coagulant addition and all plant flow must pass through basins.
Two-stage lime softening	0.5-log credit for two-stage softening where chemical addition and hardness precipitation occur in both stages. All plant flow must pass through both stages. Single-stage softening is credited as equivalent to conventional treatment.
Bank filtration	0.5-log credit for 25-foot setback; 1.0-log credit for 50-foot setback; horizontal and vertical wells only; aquifer must be unconsolidated sand containing at least 10 percent fines (as defined in rule); average turbidity in wells must be less than 1 NTU. PWSs using existing wells followed by filtration must monitor the well effluent to determine bin classification and are not eligible for additional credit.

TABLE IV.D–1.—MICROBIAL TOOLBOX: OPTIONS, CREDITS AND CRITERIA—Continued

Toolbox option	Cryptosporidium treatment credit with design and operational criteria [1]
Treatment Performance Toolbox Options	
Combined filter performance	0.5-log credit for combined filter effluent turbidity less than or equal to 0.15 NTU in at least 95 percent of measurements each month.
Individual filter performance	0.5-log credit (in addition to 0.5-log combined filter performance credit) if individual filter effluent turbidity is less than or equal to 0.15 NTU in at least 95 percent of samples each month in each filter and is never greater than 0.3 NTU in two consecutive measurements in any filter.
Demonstration of performance	Credit awarded to unit process or treatment train based on a demonstration to the State with a State-approved protocol.
Additional Filtration Toolbox Options	
Bag and cartridge filters	Up to 2-log credit with demonstration of at least 1-log greater removal in a challenge test when used singly. Up to 2.5-log credit with demonstration of at least 0.5-log greater removal in a challenge test when used in series.
Membrane filtration	Log credit equivalent to removal efficiency demonstrated in challenge test for device if supported by direct integrity testing.
Second stage filtration	0.5-log credit for second separate granular media filtration stage if treatment train includes coagulation prior to first filter.
Slow sand filters	2.5-log credit as a secondary filtration step; 3.0-log credit as a primary filtration process. No prior chlorination.
Inactivation Toolbox Options	
Chlorine dioxide	Log credit based on measured CT in relation to CT table.
Ozone	Log credit based on measured CT in relation to CT table.
UV	Log credit based on validated UV dose in relation to UV dose table; reactor validation testing required to establish UV dose and associated operating conditions.

[1] Table provides summary information only; refer to following preamble and regulatory language for detailed requirements.

2. Watershed Control Program

a. Today's Rule

Filtered PWSs can receive 0.5-log credit toward Cryptosporidium treatment requirements under today's rule for implementing a State-approved watershed control program designed to reduce the level of Cryptosporidium. To be eligible to receive this credit initially, PWSs must perform the following steps:

- Notify the State of the intent to develop a new or continue an existing watershed control program for Cryptosporidium treatment credit no later than two years prior to the date the PWS must comply with additional Cryptosporidium treatment requirements under today's rule.
- Submit a proposed watershed control plan to the State for approval no later than one year prior to the date the PWS must comply with additional Cryptosporidium treatment requirements under today's rule. The watershed control plan must contain these elements:

(1) The designation of an ''area of influence'' in the watershed, which is defined as the area outside of which the likelihood of Cryptosporidium contamination affecting the treatment plant intake is not significant;

(2) The identification of both potential and actual sources of Cryptosporidium contamination, including a qualitative assessment of the relative impact of these contamination sources on water quality at the treatment plant intake;

(3) An analysis of control measures that could mitigate the sources of Cryptosporidium contamination, including the relative effectiveness of control measures in reducing Cryptosporidium loading to the source water and their feasibility; and

(4) A statement of goals and specific actions the PWS will undertake to reduce source water Cryptosporidium levels, including a description of how the actions will contribute to specific goals, watershed partners and their roles, resource requirements and commitments, and a schedule for plan implementation.

If the State approves the watershed control plan for Cryptosporidium treatment credit, PWSs must perform the following steps to be eligible to maintain the credit:

- Submit an annual watershed control program status report to the State no later than a date specified by the State. The status report must describe the following: (1) how the PWS is implementing the approved watershed control plan; (2) the adequacy of the plan to meet its goals; (3) how the PWS is addressing any shortcomings in plan implementation; and (4) any significant changes that have occurred in the watershed since the last watershed sanitary survey.
- Notify the State prior to making any significant changes to the approved watershed control plan. If any change is likely to reduce the planned level of source water protection, the PWS must include in this notification a statement of actions that will be taken to mitigate this effect.
- Perform a watershed sanitary survey no less frequently than the PWS must undergo a sanitary survey under 40 CFR 142.16(b)(3)(i), which is every three to five years, and submit the survey report to the State for approval. The State may require a PWS to perform a watershed sanitary survey at an earlier date if the State determines that significant changes may have occurred in the watershed since the previous sanitary survey. A person approved by the State must conduct the watershed sanitary survey and the survey must meet applicable State guidelines. The watershed sanitary survey must encompass the area of influence as identified in the State-approved watershed control plan, assess the implementation of actions to reduce source water Cryptosporidium levels, and identify any significant new sources of Cryptosporidium.

PWSs are eligible to receive Cryptosporidium treatment credit under today's rule for preexisting watershed control programs (e.g., programs in place at the time of rule promulgation).

To be eligible for credit, such programs must meet the requirements stated in this section and the watershed control plan must address future actions that will further reduce source water Cryptosporidium levels.

If the State determines that a PWS is not implementing the approved watershed control plan (i.e., the PWS is not carrying out the actions on the schedule in the approved plan), the State may revoke the Cryptosporidium treatment credit for the watershed control program. Failure by a PWS to demonstrate treatment credit at least equal to its Cryptosporidium treatment requirement under today's rule due to such a revocation of credit is a treatment technique violation. The violation lasts until the State determines that the PWS is implementing an approved watershed control plan or is otherwise achieving the required level of Cryptosporidium treatment credit.

PWSs must make the approved watershed control plan, annual status reports, and watershed sanitary surveys available to the public upon request. These documents must be in a plain language style and include criteria by which to evaluate the success of the program in achieving plan goals. If approved by the State, the PWS may withhold portions of these documents based on security considerations.

Unfiltered PWSs are not eligible to receive Cryptosporidium treatment credit for a watershed control program under today's rule. Under existing regulations (40 CFR 141.71), unfiltered PWSs must maintain a watershed control program that minimizes the potential for contamination by Cryptosporidium as a condition for avoiding filtration.

b. Background and Analysis

Cryptosporidium enters drinking water through fecal contamination of PWS source waters. Implementing a watershed control program that reduces or treats sources of fecal contamination in PWS sources will benefit public health by lowering the exposure of drinking water consumers to Cryptosporidium and other pathogenic microorganisms. In addition, a watershed control program may enhance treatment plant management practices through generating knowledge of the sources, fate, and transport of pathogens.

The Stage 2 M–DBP Advisory Committee recommended 0.5-log Cryptosporidium treatment credit for a watershed control program (USEPA 2000a), and the August 11, 2003 proposal included criteria for PWSs to receive this credit (USEPA 2003a). The following discussion summarizes the basis for this credit and for differences in associated requirements between the proposal and today's final rule.

The efficacy of a watershed control program in reducing levels of Cryptosporidium and other microbial pathogens depends on the ability of a PWS to identify and control sources of fecal contamination. The fecal sources that are significant in a particular watershed and the control measures that will be effective in mitigating these sources are site specific. Consequently, EPA believes that States should determine whether a watershed control program developed by a PWS to reduce Cryptosporidium contamination warrants 0.5-log treatment credit. Accordingly, today's rule requires State approval of watershed control programs for PWSs to receive credit.

If a PWS intends to implement a watershed control program to comply with Cryptosporidium treatment requirements under today's rule, EPA believes the PWS should notify the State at least two years prior to the required treatment compliance date. This notification will give the State an opportunity to communicate with the PWS regarding site-specific considerations for a watershed control program. Further, the PWS should submit the proposed watershed control plan to the State for approval at least one year prior to the treatment compliance date. This schedule will give the State time to evaluate the program for approval and, if necessary, allow the PWS to make modifications necessary for approval. Thus, today's rule establishes these reporting deadlines.

The required elements for a watershed control plan in today's rule are the minimum necessary for a program that will be effective in reducing levels of Cryptosporidium and other pathogens in a treatment plant intake. These elements include defining the area of the watershed where contamination can affect the intake water quality, identifying sources of contamination within this area, evaluating control measures to reduce contamination, and developing an action plan to implement specific control measures.

EPA encourages PWSs to leverage other Federal, State, and local programs in developing the elements of their watershed control plans. For example, SDWA section 1453 requires States to carry out a source water assessment program (SWAP) for PWSs. Depending on how a State implements this program, the SWAP may be used to define the area of influence in the watershed and identify actual and potential contamination sources. In 2002, EPA launched the Watershed Initiative (67 FR 36172, May 23, 2002) (USEPA 2002b), which will provide grants to support watershed-based approaches to preventing, reducing, and eliminating water pollution. In addition, EPA recently promulgated regulations for Concentrated Animal Feeding Operations that will limit discharges that contribute microbial pathogens to watersheds.

Many PWSs do not control the watersheds of their sources of supply. Their watershed control plans should involve partnerships with watershed landowners and government agencies that have authority over activities in the watershed that may contribute Cryptosporidium to the water supply. Stakeholders that control activities that could contribute to Cryptosporidium contamination include municipal government and private operators of wastewater treatment plants, livestock farmers and persons who spread manure, individuals with failing septic systems, logging operations, and other government and commercial organizations.

After a State approves a watershed control plan for a PWS and initially awards 0.5-log Cryptosporidium treatment credit, the PWS must submit a watershed control program status report to the State each year. These reports are required for States to exercise oversight and ensure that PWSs implement the approved watershed control plan. They also provide a mechanism for PWSs to work with the States to address any shortcomings or necessary modifications in watershed control plans that are identified after plan approval.

In addition, PWSs must undergo watershed sanitary surveys every three to five years by a State-approved party. These surveys will provide information to PWSs and States regarding significant changes in the watershed that may warrant modification of the approved watershed control plan. Also, they allow for an assessment of watershed control plan implementation.

The proposed rule required watershed sanitary surveys annually, but EPA has reduced the frequency to every three to five years in today's final rule. This frequency is consistent with existing requirements for PWS sanitary surveys. EPA is establishing this longer frequency on the basis that most watersheds will not undergo significant changes over the course of a single year. If significant changes in the watershed do occur, however, PWSs must identify these changes in their annual program status reports. In addition, States have

the authority to require that a watershed sanitary survey be conducted at an earlier date if the State determines that significant changes may have occurred in the watershed since the previous survey.

In the proposed rule, approval of a watershed control program expired after a PWS completed the second round of source water monitoring, and the PWS had to reapply for program approval. Today's final rule, however, does not include this requirement. Instead, today's rule gives States authority to revoke Cryptosporidium treatment credit for a watershed control program at any point if a State determines that a PWS is not implementing the approved watershed control plan. EPA believes this approach is preferable to the automatic expiration of credit in the proposed rule for two reasons: (1) It assures PWSs that if they implement the approved watershed control plan, they will maintain the treatment credit; and (2) it gives States the authority to ensure PWSs implement watershed control programs for which they receive treatment credit and to take action at any time if a PWS does not.

EPA believes that PWSs should be eligible to receive Cryptosporidium treatment credit for watershed control programs that are in place prior to the treatment compliance date. The same requirements for watershed control program treatment credit apply regardless of whether the program is new or existing at the time the PWS submits the watershed control plan for approval. In the case of existing programs, the watershed control plan must list future activities the PWS will undertake that will reduce source water contamination.

The Toolbox Guidance Manual lists programmatic resources and guidance available to assist PWSs in building partnerships and implementing watershed protection activities. It also incorporates information on the effectiveness of different control measures to reduce Cryptosporidium levels and provides case studies of watershed control programs. This guidance is intended to assist both PWSs in developing watershed control programs and States in assessing and approving these programs.

In addition to this guidance and other technical resources, EPA provides funding for watershed and source water protection through the Drinking Water State Revolving Fund (DWSRF) and Clean Water State Revolving Fund (DWSRF). Under the DWSRF program, States may fund source water protection activities by PWSs, including watershed management and pathogen source reduction plans. CWSRF funds can be used for agricultural best management practices to reduce pathogen loading in receiving waters and for the replacement of failing septic systems.

c. Summary of Major Comments

Public comments on the August 11, 2003, LT2ESWTR proposal supported the concept of awarding credit towards Cryptosporidium treatment requirements for an effective watershed control program. Commenters expressed concerns, however, with specific criteria for awarding this credit, including annual watershed sanitary surveys, re-approval of watershed control programs, standards for existing watershed control programs, and public availability of documents related to the watershed control program. A summary of these comments and EPA's responses follows.

Regarding the proposed requirement for annual watershed sanitary surveys, commenters stated that this frequency is too high because activities to reduce Cryptosporidium contamination in the watershed will often take many years to implement. These commenters recommended that watershed sanitary surveys be performed every three to five years in conjunction with PWSs sanitary surveys or longer. In contrast, other commenters supported annual watershed sanitary surveys as being necessary to allow proper responses to new sources of contamination that can occur quickly in watersheds. Such sources can occur through development, new recreation programs, fires, unauthorized activities, and other factors.

While EPA believes that regular watershed sanitary surveys are necessary to identify new sources of contamination and allow States to properly oversee watershed control programs, EPA agrees that significant changes typically will not occur over one year. Therefore, today's final rule requires PWSs that receive Cryptosporidium treatment credit for a watershed control program to undergo watershed sanitary surveys every three to five years, rather than every year. To address the concern that new sources of watershed contamination can arise quickly, today's rule requires PWSs to identify any significant changes that have occurred in their watersheds in their annual program status reports. States can then require a watershed sanitary survey at an earlier date if significant changes have occurred since the previous survey.

Many commenters opposed the proposed requirement for PWSs to reapply for approval of their watershed control programs after completing the second round of source water monitoring. The concern was that this requirement would discourage PWSs from pursuing watershed control programs because they would be uncertain about whether they would continue to receive treatment credit for their programs in the future. As an alternative, commenters recommended that States monitor the progress of PWSs in implementing watershed control programs through the watershed sanitary surveys and annual status reports. A State could then deny treatment credit to a PWS if it failed to demonstrate adequate commitment to its approved watershed control plan.

EPA agrees with these comments and today's final rule does not include a requirement for re-approval of the watershed control program after the second round of monitoring. Instead, PWSs must submit annual program status reports to the State and undergo regular watershed sanitary surveys. If the State determines that a PWS is not implementing its approved watershed control plan on the basis of these measures, it can withdraw the treatment credit associated with the program. PWSs that implement their approved watershed control plans, however, can maintain the associated treatment credit indefinitely under today's rule.

Several commenters stated that PWSs with existing watershed control programs should be eligible for Cryptosporidium treatment credit under the same standards that apply to new programs. EPA agrees that both existing and new watershed control programs should be eligible for Cryptosporidium treatment credit under the same standards, and today's rule allows this. As is required for new programs, PWSs with existing watershed control programs must submit a watershed control plan that details future activities the PWS will implement to reduce source water contamination. As with new programs, States will have the discretion to approve the proposed watershed control plan for 0.5-log Cryptosporidium treatment credit.

With respect to a proposed requirement that the watershed control plan, annual status reports, and watershed sanitary surveys be made available to the public, commenters stated that homeland security concerns are associated with these documents. Homeland security concerns apply to information on the location of treatment plant intakes and other structures. EPA agrees that there are security concerns associated with watershed control program documents. EPA also believes, though, that the public should be allowed to learn about the actions PWSs

plan to take to address Cryptosporidium contamination and the progress of PWSs in implementing these actions. Consequently, today's rule requires PWSs to make the approved watershed control plan, annual status reports, and watershed sanitary surveys available to the public. However, PWSs may withhold portions of these documents that raise security concerns with State approval.

3. Alternative Source

a. Today's Rule

If approved by the State, a PWS may determine its Cryptosporidium treatment requirements under today's rule using additional source water monitoring results for an alternative treatment plant intake location or an alternative intake operational strategy. By meeting the requirements of this option, which are described as follows, a PWS may reduce its Cryptosporidium treatment requirements under today's rule.

- Monitoring for an alternative intake location or operational strategy, termed ''alternative source monitoring,'' may only be performed in addition to monitoring the existing plant intake(s) (i.e., the intake(s) the PWS uses when it must begin monitoring under today's rule).
- Alternative source monitoring must meet the sample number, sample frequency, and data quality requirements that apply to source water monitoring for bin classification, as described in section IV.A.
- PWSs that perform alternative source monitoring must complete this monitoring by the applicable deadline for treatment bin classification under today's rule, as described in section IV.G. Unless a PWS grandfathers monitoring data for the existing plant intake, alternative source monitoring must be performed concurrently with monitoring the existing intake.
- PWSs must submit the results of alternative source monitoring to the State, along with supporting information documenting the location and/or operating conditions under which the alternative source monitoring was conducted. If a PWS fulfills these requirements, the PWS may request that the State classify the PWS in a treatment bin under today's rule using the alternative source monitoring results.
- If the State approves bin classification for a PWS using alternative source monitoring results, the PWS must relocate the plant intake or implement the intake operational strategy to reflect the alternative source monitoring. The PWS must complete these actions no later than the applicable date for the PWS to comply with Cryptosporidium treatment requirements under today's rule. The State may specify reporting requirements to verify operational practices.

Failure by a PWS that is classified in a treatment bin using alternative source monitoring to relocate the intake or implement the new intake operational strategy, as required, by the applicable treatment compliance deadline is a treatment technique violation. This violation lasts until the State determines that the PWS has carried out required changes to the intake location or operation or is providing the level of Cryptosporidium treatment required for the existing intake location and operation.

b. Background and Analysis

Plant intake refers to the works or structures at the head of a conduit through which water is diverted from a source (e.g., river or lake) into a treatment plant. Plants may be able to reduce influent Cryptosporidium levels by changing the intake placement (either within the same source or to an alternate source) or managing the timing or level of withdrawal.

The Stage 2 M–DBP Advisory Committee recommended that PWSs be allowed to modify their plant intakes to comply with today's rule, and the August 11, 2003 proposal included this option (USEPA 2000a). The requirements for this option in today's final rule are unchanged from the proposal. The following discussion summarizes the basis for these requirements.

The effect of changing the location or operation of a plant intake on influent Cryptosporidium levels can only be ascertained through monitoring. Consequently, EPA is not establishing a prescriptive credit for this option. Rather, if a PWS expects that Cryptosporidium levels from a current plant intake will result in a bin classification requiring additional treatment under today's rule, the PWS may conduct additional Cryptosporidium monitoring reflecting a different intake location or operational strategy (alternative source monitoring). The PWS may then request that the State approve bin classification for the plant based on alternative source monitoring results, provided the PWS will implement the corresponding changes to the intake location or operation.

PWSs that conduct alternative source monitoring must also monitor their existing plant intakes. Monitoring the existing intake is required for the State to determine a treatment bin classification for a plant in the event the PWS does not modify the intake (to reflect alternative source monitoring) prior to the treatment compliance deadline under today's rule.

Further, PWSs must conduct alternative source monitoring within the applicable time frame for source water monitoring under today's rule. This approach is required for the State to determine a bin classification for the plant based on alternative source monitoring by the bin classification deadline. In addition, this timing will allow the PWS to modify the intake or implement additional treatment, if necessary, by the treatment compliance deadline. This requirement means, however, that unless a PWS meets the requirement for monitoring its existing intake through grandfathering, the PWS must perform alternative source monitoring concurrently with existing intake monitoring, although it does not have to be on exactly the same schedule.

Because alternative source monitoring will be used for bin classification, this monitoring must comply with all applicable requirements for source water monitoring that are described in section IV.A. Further, the PWS must provide the State with supporting information documenting the conditions, such as the source location, under which the alternative source monitoring was conducted. This documentation is required so that if bin classification is based on alternative source monitoring results, the State can ensure the PWS implements the corresponding modifications to the intake.

c. Summary of Major Comments

Public comments on the August 11, 2003, LT2ESWTR proposal supported allowing PWSs to determine treatment bin classification by monitoring for an alternative intake location or operational strategy. Several commenters stated they were unsure if this option would be widely used due to the burden of performing Cryptosporidium monitoring at both the current intake and the alternative source. Commenters also recommended that PWSs first conduct source water assessments or watershed sanitary surveys to evaluate intake management strategies to reduce Cryptosporidium levels in the plant influent.

In response, EPA believes that PWSs who choose alternative source monitoring must also monitor their current intake so that the State can determine the appropriate bin classification if the PWS does not

subsequently modify its intake. While few PWSs may choose to pursue alternative source monitoring, EPA believes this option should be available for PWSs that elect to do so. EPA agrees that it is appropriate for PWSs to assess contamination sources in the watershed when considering whether to relocate or change the operation of their intakes. The Toolbox Guidance Manual provides direction to PWSs on conducting these assessments.

EPA requested comment on whether representative Cryptosporidium monitoring can be performed prior to implementation of a new intake strategy (e.g., monitoring a new source prior to constructing a new intake structure). Commenters stated that there may be situations where allowing Cryptosporidium monitoring to demonstrate a reduction in oocyst levels prior to implementation of a new intake strategy is appropriate. Incurring costs for constructing a new intake before determining whether the strategy will reduce oocyst levels is not cost effective. EPA agrees with this comment and today's rule allows PWSs to conduct alternative source monitoring prior to constructing a new intake and to base their bin classification on these monitoring results with State approval.

4. Pre-Sedimentation With Coagulant

a. Today's Rule

Presedimentation is a preliminary treatment process used to remove gravel, sand and other particulate material from the source water through settling before the water enters the primary clarification and filtration processes in a treatment plant. PWSs receive 0.5-log credit towards Cryptosporidium treatment requirements under today's rule for a presedimentation process that meets the following conditions:

- Treats all flow reaching the treatment plant;
- Continuously adds a coagulant to the presedimentation basin;
- Achieves one of the following two performance criteria:

(1) Demonstrates at least 0.5-log mean reduction of influent turbidity. This reduction must be determined using daily turbidity measurements in the presedimentation process influent and effluent and must be calculated as follows: $\log_{10}$ (monthly mean of daily influent turbidity)—$\log_{10}$ (monthly mean of daily effluent turbidity).

(2) Complies with State-approved performance criteria that demonstrate at least 0.5-log mean removal of micron-sized particulate material, such as aerobic spores, through the presedimentation process.

PWSs may receive treatment credit for a presedimentation process during any month the process meets these conditions. To be eligible for credit, PWSs must report compliance with these conditions to the State each month. PWSs may earn presedimentation treatment credit for only part of the year if the process does not meet these conditions year-round. In this situation, PWSs must fully meet their Cryptosporidium treatment requirements under today's rule using other microbial toolbox options during those months when the PWS does not receive treatment credit for presedimentation.

Alternatively, PWSs may apply to the State for Cryptosporidium treatment credit for presedimentation processes using a demonstration of performance, as described in section IV.D.9. Demonstration of performance provides an option for PWSs with presedimentation processes that do not meet these prescribed conditions for treatment credit and for PWSs who seek greater than 0.5-log Cryptosporidium treatment credit for their presedimentation processes.

PWSs are not eligible for Cryptosporidium treatment credit for a presedimentation process if their sampling point for the source water Cryptosporidium monitoring used for bin classification was after (*i.e.*, downstream of) the presedimentation process. In this case, the removal achieved by the presedimentation process will be reflected in the monitoring results and bin classification.

b. Background and Analysis

Presedimentation involves passing raw water through retention basins in which particulate material is removed through settling. PWSs use presedimentation to reduce and stabilize particle concentrations prior to the primary clarification and filtration processes in a treatment plant. Presedimentation is often operated at higher hydraulic overflow rates than conventional sedimentation (the sedimentation process that directly precedes filtration in a conventional treatment plant) and may not involve coagulant addition. PWSs may operate a presedimentation process only during periods of high raw water turbidity.

As a process for removing particles, presedimentation can reduce Cryptosporidium levels to some degree. In addition, presedimentation can improve the performance of subsequent treatment processes by dampening variability in raw water quality. The efficacy of presedimentation in removing particles, including Cryptosporidium, is influenced by the use of coagulant, the hydraulic loading rate, water quality parameters like temperature and turbidity, and physical characteristics of the sedimentation basin.

The Stage 2 M–DBP Advisory Committee recommended 0.5-log Cryptosporidium treatment credit for presedimentation with coagulation (USEPA 2000a). The August 11, 2003 proposal included criteria, which were similar to those in today's final rule, for PWSs to receive this credit (USEPA 2003a). The following discussion summarizes the basis for this credit and for differences in associated requirements between the proposal and today's final rule.

In the proposal, EPA reviewed published studies of Cryptosporidium removal through conventional sedimentation processes by Payment and Franco (1993), Kelly et al. (1995), Patania et al. (1995), States et al. (1997), Edzwald and Kelly (1998), and Dugan et al. (2001). These studies included bench-, pilot-, and full-scale processes, and the reported levels of Cryptosporidium removal varied widely, ranging from 0.4- to 3.8-log. In addition, these studies also supported two other significant findings:

(1) Proper coagulation significantly improves Cryptosporidium removal through sedimentation. In Dugan et al. (2001), for example, average Cryptosporidium removal across a sedimentation basin was 1.3-log with optimal coagulation and decreased to 0.2-log when the coagulant dose was insufficient.

(2) The removal of aerobic spores correlates well with the removal of Cryptosporidium when a coagulant is present. This indicates that aerobic spores, which are naturally present in surface waters, may be used as an indicator of Cryptosporidium removal in coagulated full-scale sedimentation processes.

Cryptosporidium removal efficiencies in conventional sedimentation may be higher than in presedimentation due to differences in hydraulic loading rates, coagulant doses, and other factors. EPA identified no published studies of Cryptosporidium removal through presedimentation processes. In the proposal, however, EPA evaluated data on the removal of aerobic spores in the presedimentation processes of three PWSs as an indicator of Cryptosporidium removal (USEPA 2003a). All three PWSs added a coagulant (polymer, metal salts, or recycled sludge) to the presedimentation process. The mean removal of aerobic spores through presedimentation in the three PWSs ranged from 0.5- to 1.1-log over time

spans ranging from several months to several years.

These data support the finding that full-scale presedimentation processes can achieve Cryptosporidium removals of 0.5-log and greater under routine operating conditions and over an extended time period. Accordingly, EPA concluded that 0.5-log Cryptosporidium treatment credit for presedimentation processes is appropriate under certain conditions. Today's rule establishes three conditions for PWSs to receive this credit.

The first condition for presedimentation to receive 0.5-log Cryptosporidium treatment credit is that the process must treat all flow reaching the treatment plant. Presedimentation cannot reduce the Cryptosporidium level entering a treatment plant by 0.5-log or greater on a continuous basis if the process is operated intermittently or treats only a fraction of the plant flow. EPA recognizes that for some PWSs, operating a presedimentation process intermittently in response to high turbidity levels is preferable to continuous operation. By establishing a requirement for continuous operation as a condition for treatment credit, EPA is not recommending against intermittent operation of presedimentation processes. Rather, EPA is only identifying one of the conditions under which a 0.5-log Cryptosporidium treatment credit for presedimentation appears to be justified.

A second condition for presedimentation treatment credit is that the process must operate with coagulant addition. Available data support awarding 0.5-log Cryptosporidium treatment credit to a presedimentation process only when a coagulant is present. The full-scale presedimentation data reviewed in the proposal involved coagulant addition, and literature studies indicate that Cryptosporidium removal through sedimentation can be substantially lower in the absence of sufficient coagulant. Further, the Stage 2 M–DBP Advisory Committee specifically recommended 0.5-log Cryptosporidium treatment credit for presedimentation with coagulation (USEPA 2000a). Based on these factors, EPA concluded that coagulation is a necessary condition for PWSs to receive treatment credit for presedimentation.

The third condition for awarding treatment credit to presedimentation is that the process must achieve a monthly mean turbidity reduction of at least 0.5-log or meet alternative State-approved performance criteria. This requirement stems from a recommendation by the SAB, which reviewed data for awarding treatment credit to presedimentation under the LT2ESWTR. In their report, the SAB concluded that available data were minimal to support 0.5-log prescribed credit for presedimentation and recommended that performance criteria other than overflow rate be included if credit is given for presedimentation (SAB 2003).

In response to this recommendation by the SAB, EPA analyzed the relationship between removal of aerobic spores (as an indicator of Cryptosporidium removal) and reduction in turbidity in the full-scale presedimentation processes of three PWSs. The results of this analysis, which are shown in Table IV.D–2, suggest that presedimentation processes achieving a monthly mean reduction in turbidity of at least 0.5-log have a high likelihood of reducing mean Cryptosporidium levels by 0.5-log or more. Consequently, EPA concluded that turbidity reduction is an appropriate performance criterion for awarding Cryptosporidium treatment credit to presedimentation basins. The Agency believes this performance criterion addresses the concern raised by the SAB.

TABLE IV.D–2.—RELATIONSHIP BETWEEN MEAN TURBIDITY REDUCTION AND THE PERCENT OF MONTHS WHEN MEAN SPORE REMOVAL WAS AT LEAST 0.5 LOG

Log reduction in turbidity (monthly mean)	Percent of months with at least 0.5 Log Mean Reduction in spores (percent)
at least 0.1-log	64
at least 0.2-log	68
at least 0.3-log	73
at least 0.4-log	78
at least 0.5-log	89
at least 0.6-log	91
at least 0.7-log	90
at least 0.8-log	89
at least 0.9-log	95
at least 1.0-log	96

Source: Data from Cincinnati Water Works, Kansas City Water Services Department, and St. Louis Water Division.

The proposed rule required PWSs to achieve at least 0.5-log turbidity reduction through presedimentation in at least 11 of the 12 previous consecutive months to be eligible for presedimentation treatment credit. EPA recognizes, however, that some PWSs will not be able to demonstrate at least 0.5-log turbidity reduction through presedimentation during months when raw water turbidity is lower. As a result, these PWSs would not be able to achieve treatment credit for their presedimentation basins. To provide more options for these PWSs, EPA has modified this requirement in today's final rule in two respects.

The first modification is that in today's final rule, PWSs must demonstrate compliance with the conditions for presedimentation treatment credit on a monthly, rather that a yearly basis. This requirement allows treatment credit for presedimentation in any month a PWS can demonstrate at least 0.5-log turbidity reduction, even if the PWS cannot achieve this level of turbidity reduction in all months of the year.

A PWS that meets the conditions for presedimentation treatment credit for only part of the year must implement other microbial toolbox options to comply with Cryptosporidium treatment requirements in the remainder of the year. Nevertheless, achieving presedimentation treatment credit for even part of the year may benefit certain PWSs. For example, a PWS may be able to reduce the level of disinfection it provides during the months it receives presedimentation treatment credit, or this treatment credit may provide a margin of safety to ensure compliance with Cryptosporidium treatment requirements.

The second modification is the allowance for States to approve alternative performance criteria to turbidity reduction that demonstrate at least 0.5-log mean removal of micron-sized particulate material through the presedimentation process. EPA believes that aerobic spores are an appropriate alternative criterion. As described earlier, studies support the use of aerobic spores as an indicator of Cryptosporidium removal in coagulated sedimentation processes. If approved by the State, a PWS could receive 0.5-log treatment credit for presedimentation by demonstrating at least 0.5-log reduction in aerobic spores. The Toolbox Guidance Manual provides information on analytical methods for measuring aerobic spores. This may provide an option for PWSs that are not able to demonstrate 0.5-log turbidity reduction but have a sufficient concentration of aerobic spores in their raw water. PWSs may work with States to identify other alternative criteria, as well as appropriate monitoring to support use of the criteria.

c. Summary of Major Comments

Public comments on the August 11, 2003, LT2ESWTR proposal supported allowing PWSs to achieve 0.5-log credit towards Cryptosporidium treatment requirements for presedimentation with

coagulation. Some commenters also supported the proposed operational, monitoring, and performance conditions required for PWSs to receive this credit. Other commenters, however, opposed the proposed requirement for turbidity reduction as a condition for receiving presedimentation treatment credit. A summary of these commenters' concerns and EPA's responses follows.

Commenters who opposed requiring turbidity reduction for presedimentation treatment credit were concerned that PWSs cannot achieve this criterion during periods when raw water turbidity is low. Further, these commenters stated that turbidity removal does not reflect the overall benefits of presedimentation, which improves the performance of the primary treatment train by equalizing water quality. Some commenters also provided data showing the reduction in turbidity and aerobic spore levels in the presedimentation processes of several PWSs and stated that turbidity removal may not be an appropriate indicator of acceptable performance for presedimentation basins. Several commenters suggested that EPA establish a limit on hydraulic overflow rate in place of a turbidity removal requirement.

In response, EPA continues to believes that 0.5-log turbidity reduction is an appropriate performance indicator for 0.5-log Cryptosporidium reduction in presedimentation processes. EPA has reviewed the additional data submitted by commenters on the removal of turbidity and aerobic spores (as an indicator of Cryptosporidium removal) in full-scale presedimentation basins. These data are consistent with data reviewed for the proposal in showing that when turbidity removal was below 0.5-log, removal of aerobic spores was also usually below 0.5-log. Conversely, when turbidity reduction exceeded 0.5-log, aerobic spore removal was typically higher than 0.5-log. Consequently, while there is not a one-to-one relationship between reduction in turbidity and reduction in aerobic spores, 0.5-log turbidity reduction is a reasonable indicator of when Cryptosporidium removal is likely to be at least 0.5-log.

EPA recognizes, though, that 0.5-log turbidity reduction through presedimentation will not be feasible for some PWSs when raw water turbidity is low. Today's final rule contains several provisions to address this concern. First, PWSs can receive credit for presedimentation during any month the process achieves 0.5-log turbidity removal. Thus, PWSs that cannot achieve 0.5-log turbidity reduction year-round may receive credit for presedimentation in those months when they can meet this condition. Today's rule also allows PWSs to receive presedimentation credit using State-approved performance criteria other than turbidity reduction. If approved by the State, a PWS may receive credit for presedimentation by demonstrating, for example, 0.5-log reduction in aerobic spores. Finally, if presedimentation improves treatment plant performance by reducing and equalizing particle loading, a PWS can receive additional treatment credit under today's rule for achieving lower filtered water turbidity (see section IV.D.7).

5. Two-Stage Lime Softening

a. Today's Rule

Lime softening in drinking water treatment involves the addition of lime and other chemicals to remove hardness (calcium and magnesium) through precipitation. In single-stage softening, chemical addition and hardness precipitation occur in a single clarification process prior to filtration. In two-stage softening, chemical addition and hardness precipitation occur in each of two sequential clarification processes prior to filtration. In some water treatment plants, a portion of the raw water bypasses a softening process (i.e., split softening) in order to achieve a desired pH and alkalinity level in the treated water.

Under today's rule, single-stage softening with filtration receives a prescribed 3.0-log credit towards Cryptosporidium treatment requirements, which is equivalent to conventional treatment (see section IV.B). Two-stage softening receives an additional 0.5-log Cryptosporidium treatment credit during any month a PWS meets the following conditions:

(1) Chemical addition and hardness precipitation occur in two separate and sequential softening stages prior to filtration; and

(2) Both softening stages treat the entire plant flow taken from surface water sources or GWUDI (i.e., no portion of the plant flow from a surface water source may bypass either softening stage).

Alternatively, PWSs may apply to the State for Cryptosporidium treatment credit for softening processes using a demonstration of performance, as described in section IV.D.9. Demonstration of performance provides an option for PWSs with softening processes that do not meet these conditions for prescribed treatment credit and for PWSs who seek greater than the prescribed Cryptosporidium treatment credit for their softening processes.

b. Background and Analysis

Lime softening is a common practice that PWSs use to reduce water hardness, which is primarily calcium and magnesium. The addition of lime elevates the pH of the raw water. Elevation to pH 9.4 or higher causes precipitation of calcium carbonate and further elevation to pH 10.6 or higher causes precipitation of magnesium hydroxide. Soda ash may be added with lime to precipitate non-carbonate hardness. Removal of the precipitate occurs through clarification (e.g., sedimentation basin) and filtration processes. Coagulants and recycled softening sludge are often used to enhance removal. In two-stage softening, the second stage is commonly used to precipitate magnesium, along with increased levels of calcium.

In addition to reducing hardness, softening processes remove particulate material present in the raw water, including microbial pathogens like Cryptosporidium. Particulate material flocculates with the softening precipitate and is removed through the clarification and filtration processes, similar to a conventional treatment plant. The degree of Cryptosporidium removal will depend on the amount of precipitate formation, the use of coagulants, the raw water quality, and other factors. Available data indicate that the elevated pH used in softening does not inactivate Cryptosporidium or Giardia (Logsdon et al. 1994, Li et al. 2001), though it does inactivate some microorganisms like viruses (Battigelli and Sobsey, 1993, Logsdon et al. 1994).

The Stage 2 M–DBP Advisory Committee recommended that lime softening be eligible for up to 1.0-log additional Cryptosporidium treatment credit based on a site-specific demonstration of performance, but did not recommend any prescribed credit for this process (USEPA 2000a). After reviewing available data, however, EPA included a prescribed 0.5-log Cryptosporidium treatment credit for two-stage lime softening in the August 11, 2003 proposal (USEPA 2003a). This approach reflected a recommendation by the SAB, which supported an additional 0.5-log treatment credit for two-stage lime softening if all the water passes through both stages (SAB 2003). The proposal also allowed for greater treatment credit through a demonstration of performance. The following discussion summarizes the basis for the lime softening treatment credit in today's final rule and differences with the proposal.

In the proposal, EPA reviewed a study by Logsdon et al. (1994) that evaluated

Cryptosporidium removal in full-scale lime softening plants. Cryptosporidium was detected in the raw water at 5 plants: one single-stage plant and four two-stage plants. Based on measured levels, the removal of Cryptosporidium across the softening clarification (sedimentation) stages was 1.0-log in the single stage plant and ranged from 1.1- to 2.3-log in the two-stage plants. Cryptosporidium reductions from raw to filtered water were 0.6- and 2.2-log in the single stage plant and ranged from greater than 2.67- to greater than 3.85-log in the two-stage plants.

EPA also evaluated data collected by PWSs on the removal of aerobic spores in full-scale lime softening plants. As discussed earlier, studies have shown the removal of aerobic spores to be an indicator for Cryptosporidium removal, and one pilot-scale study of a softening plant found significantly greater removal of Cryptosporidium than aerobic spores under similar treatment conditions (Clark et al., 2001). For the full-scale plants, average reductions in aerobic spores across the softening clarification stages were 2.4- and 2.8-log for two plants that practice two-stage softening and were 1.6- and 2.4-log for two plants that practice single-stage softening (USEPA 2003a).

The Cryptosporidium removal data from Logsdon et al. (1994) and the aerobic spore removal data provided by PWSs indicate that a lime softening clarification stage can achieve greater than 0.5-log Cryptosporidium removal during routine operation. Consequently, EPA agrees with the SAB recommendation to award an additional 0.5-log Cryptosporidium treatment credit for two-stage softening. Today's rule establishes two-conditions for PWSs to receive this credit.

The first condition for 0.5-log treatment credit for two-stage softening is that chemical addition and hardness precipitation must occur in two separate and sequential softening stages prior to filtration. The purpose of this condition is to ensure that plants receiving additional credit for two-stage softening actually have softening and associated particle removal occurring in each of two sequential clarification stages. Plants with other types of clarification processes in series with a softening stage are not eligible for two-stage softening credit. Such plants may, however, be eligible for additional treatment credit for other microbial toolbox options, such as presedimentation, or may achieve additional credit through a demonstration of performance.

The second condition for two-stage softening treatment credit is that both softening stages must treat the entire plant flow taken from a surface water source or GWUDI. The SAB recommended this condition, which reflects the understanding that a softening stage is unlikely to reduce overall Cryptosporidium levels by 0.5-log or more if it treats only a fraction of the plant flow.

EPA recognizes that some PWSs using softening will bypass a softening stage in order to maintain a desired pH and alkalinity level in the treated water, and EPA is not recommending against this practice generally. Rather, the restriction on bypassing a softening stage in today's rule applies only to PWSs that seek additional treatment credit for softening. Additionally, plants that soften both surface water and ground water are eligible for softening treatment credit if they bypass a softening stage only with ground water that is not under the direct influence of surface water.

The proposal also required that a coagulant be present in both clarifiers for a PWS to be eligible for additional treatment credit for two-stage softening. EPA is not establishing this requirement in today's final rule. While many PWSs that practice softening add coagulants to improve the removal of precipitates and other particles, the SAB did not recommend coagulant addition as a condition for receiving treatment credit. Further, available data do not indicate that additional coagulant is necessary to achieve at least 0.5-log Cryptosporidium removal across a softening clarification stage if hardness precipitation is occurring.

c. Summary of Major Comments

Public comments on the August 11, 2003, LT2ESWTR proposal supported awarding additional Cryptosporidium treatment credit for lime softening processes. EPA received specific comments on the types of lime softening processes eligible for additional treatment credit, the amount of additional treatment credit awarded, and the need for a coagulant. A summary of these commenters' concerns and EPA's responses follows.

In regard to the types of lime softening processes eligible for treatment credit, commenters recommended that EPA better define two-stage softening. Commenters stated that two-stage softening involves two separate reaction chambers with the addition of the softening chemical at the beginning of each chamber. Some commenters recommended that eligibility for additional treatment credit should be based on the level of softening precipitate formed or the settled water turbidity and not on whether a plant practices single- or two-stage softening. Another commenter recommended that any plant designs with multiple, continuously operated clarification processes in series should be eligible for additional treatment credit.

In response, EPA has refined the definition of two-stage softening in today's final rule, which requires that softening processes employ chemical addition and hardness precipitation in two sequential stages to be eligible for the prescribed additional treatment credit. EPA agrees with commenters that the level of precipitate formation will influence the degree of Cryptosporidium removal. Available data, however, indicate that two-stage softening will generally achieve more Cryptosporidium removal than single-stage softening. Consequently, EPA believes that two-stage softening should be eligible for the additional prescribed 0.5-log treatment credit. Plants with single-stage softening may receive additional treatment credit under today's rule through a demonstration of performance. Similarly, plants that employ multiple clarification process other than softening in series may receive additional treatment credit either as presedimentation or through a demonstration of performance.

With respect to the amount of additional Cryptosporidium treatment credit for two-stage softening, most commenters supported awarding 3.0-log treatment credit to single-stage lime softening, equivalent to a conventional treatment plant, and an additional prescribed 0.5-log treatment credit for two-stage lime softening. A few commenters requested that two-stage lime be granted an additional Cryptosporidium treatment credit of 1.0-log, based on the level of aerobic spore removal measured across softening clarifiers.

EPA agrees with most commenters and the SAB that 0.5-log is an appropriate level of additional prescribed Cryptosporidium treatment credit for two-stage softening. Where plants are able to demonstrate a significantly higher level of removal of Cryptosporidium or an indicator like aerobic spores, they may apply for additional treatment credit through a demonstration of performance.

Commenters stated that achieving particle removal in lime softening is not dependent on a coagulant like a metal salt or organic polymer. Some commenters recommended that coagulant be defined to include softening chemicals like lime and magnesium hydroxide (a softening

precipitate). EPA agrees that available data do not demonstrate the need for a traditional metal salt or organic coagulant for effective particle removal in softening. Accordingly, today's final rule does not require the use of a coagulant as a condition for additional treatment credit in two-stage softening. Instead, each stage must involve chemical addition and hardness precipitation. EPA intends this requirement to ensure that softening and associated particle removal occur in each stage if a plant is to receive additional treatment credit for two-stage softening.

6. Bank Filtration

a. Today's Rule

Bank filtration is a water treatment process that uses one or more pumping wells to induce or enhance natural surface water infiltration and to recover that surface water from the subsurface after passage through a river bed or bank(s). Under today's rule, bank filtration that serves as pretreatment to a filtration plant is eligible for Cryptosporidium treatment credit if it meets the following criteria:

- Wells with a ground water flow path of at least 25 feet receive 0.5-log treatment credit; wells with a ground water flow path of at least 50 feet receive 1.0-log treatment credit. The ground water flow path must be determined as specified in this section.
- Only wells in granular aquifers are eligible for treatment credit. Granular aquifers are those comprised of sand, clay, silt, rock fragments, pebbles or larger particles, and minor cement. A system must characterize the aquifer at the well site to determine aquifer properties. Systems must extract a core from the aquifer and demonstrate that in at least 90 percent of the core length, grains less than 1.0 mm in diameter constitute at least 10 percent of the core material.
- Only horizontal and vertical wells are eligible for treatment credit.
- For vertical wells, the ground water flow path is the measured distance from the edge of the surface water body under high flow conditions (determined by the 100 year floodplain elevation boundary or by the floodway, as defined in Federal Emergency Management Agency flood hazard maps) to the well screen. For horizontal wells, the ground water flow path is the measured distance from the bed of the river under normal flow conditions to the closest horizontal well lateral screen.
- Systems must monitor each wellhead for turbidity at least once every four hours while the bank filtration process is in operation. If monthly average turbidity levels, based on daily maximum values in the well, exceed 1 NTU, the system must report this result to the State and conduct an assessment within 30 days to determine the cause of the high turbidity levels in the well. If the State determines that microbial removal has been compromised, the State may revoke treatment credit until the system implements corrective actions approved by the State to remediate the problem.
- Springs and infiltration galleries are not eligible for treatment credit under this section, but are eligible for credit under the demonstration of performance provisions described in section IV.D.9.

Alternatively, PWSs may apply to the State for Cryptosporidium treatment credit for bank filtration using a demonstration of performance. States may award greater than 1.0-log Cryptosporidium treatment credit for bank filtration based on a site-specific demonstration. For a bank filtration demonstration of performance study, today's rule establishes the following criteria:

- The study must follow a State-approved protocol and must involve the collection of data on the removal of Cryptosporidium or a surrogate for Cryptosporidium and related hydrogeologic and water quality parameters during the full range of operating conditions.
- The study must include sampling both from the production well(s) and from monitoring wells that are screened and located along the shortest flow path between the surface water source and the production well(s).

The Toolbox Guidance Manual provides guidance on conducting site-specific bank filtration studies, including analytical methods for measuring aerobic and anaerobic spores, which may serve as surrogates for Cryptosporidium removal.

PWSs using existing bank filtration as pretreatment to a filtration plant at the time the PWS must begin source water Cryptosporidium monitoring under today's rule must sample the well for the purpose of determining bin classification. These PWSs are not eligible to receive additional treatment credit for bank filtration. In these cases, the performance of the bank filtration process in reducing Cryptosporidium levels will be reflected in the monitoring results and bin classification.

PWSs using bank filtration without additional filtration must collect source water samples in the surface water (i.e., prior to bank filtration) to determine bin classification unless the State approves an alternative monitoring location. This applies to systems using bank filtration to meet the Cryptosporidium removal requirements of the IESWTR or LT1ESWTR under the provisions for alternative filtration demonstration in 40 CFR 141.173(b) or 141.552(a). Bank filtration criteria for Cryptosporidium removal credit under today's rule do not apply to existing State actions regarding alternative filtration Cryptosporidium removal credit for IESWTR or LT1ESWTR compliance. PWSs using GWUDI sources must collect samples from the well (i.e., the ground water).

b. Background and Analysis

Bank filtration is a water treatment process that makes use of surface water that has naturally infiltrated into ground water through a river bed or bank and is recovered via a pumping well. River bed infiltration is typically enhanced by the pumping action of nearby wells. Bank filtrate is water that is drawn into a pumping well from a nearby surface water source after having traveled through the subsurface (i.e., aquifer) and mixing with other ground water. In bank filtration, microorganisms and other particles are removed by contact with the aquifer materials.

The Stage 2 M–DBP Advisory Committee recommended a prescribed Cryptosporidium treatment credit of 1.0-log for bank filtration with the option for PWSs to receive greater treatment credit through a site-specific demonstration of performance (USEPA 2000a). The August 11, 2003 proposal included criteria, similar to those in today's final rule, for PWSs to receive prescribed treatment credits of 0.5- and 1.0-log (USEPA 2000a). The following discussion summarizes the basis for these credits and for differences in associated requirements between the proposal and today's final rule.

Directly measuring the removal of Cryptosporidium through bank filtration is difficult due to the relatively low oocyst concentrations typically present in surface and ground water. In the proposal, EPA reviewed bank filtration field studies that measured the removal of Cryptosporidium surrogates, specifically aerobic and anaerobic bacterial endospores (Havelaar et al. 1995, Rice et al. 1996, Pang et al. 1998, Arora et al. 2000, Medema et al. 2000, and Wang et al. 2001). These microorganisms are suitable surrogates because they are resistant to inactivation in the subsurface, similar in size and shape to Cryptosporidium, and present in both surface and ground water at concentrations that allow calculation of log removal across the surface water-

ground water interface and within the aquifer. In addition, EPA reviewed studies of the transport of Cryptosporidium through soil materials in laboratory column studies (Harter et al. 2000).

Based on these studies, EPA concluded that bank filtration processes can achieve significant Cryptosporidium removal and that prescribed Cryptosporidium treatment credits of 0.5-log and 1.0-log are appropriate under certain conditions. These conditions are as follows: Only wells located in unconsolidated, predominantly sandy aquifers are eligible

The bank filtration removal process performs most efficiently when the aquifer is comprised of granular materials with open pore-space for water flow around the grains. In these granular porous aquifers, the flow path is meandering, thereby providing ample opportunity for microorganisms to come into contact with and attach to a grain surface. Accordingly, only wells located in unconsolidated, granular aquifers are eligible for bank filtration treatment credit.

Granular aquifers are those comprised of sand, clay, silt, rock fragments, pebbles or larger particles and minor cement. Specifically, a PWS must extract a core from the aquifer and demonstrate that in at least 90 percent of the core length, grains less than 1.0 mm in diameter constitute at least 10 percent of the core material. Laboratory column studies of Cryptosporidium transport (Harter et al., 2000) and field studies of aerobic bacterial endospore passage in the subsurface (Pang et al., 1998) support these criteria.

Only Horizontal and Vertical Wells Are Eligible

A number of devices are used for the collection of ground water including horizontal and vertical wells, spring boxes, and infiltration galleries. Among these, only horizontal and vertical wells are eligible for log removal credit because spring boxes and infiltration galleries are components of engineered systems designed to speed transport through or by-pass the naturally protective riverbed or bank.

Wells Must be Located 25 Feet From the Surface Water Source To Be Eligible for 0.5-Log Credit and Located at Least 50 Feet From the Surface Water Source To Be Eligible for 1.0-Log Credit

A vertical or horizontal well located adjacent to a surface water body is eligible for bank filtration credit if there is sufficient ground water flow path length to effectively remove oocysts. Specifically, the ground water flow path must be at least 25 feet and 50 feet for 0.5-log and 1.0-log Cryptosporidium treatment credit, respectively. The ground water flow path to a vertical well is the measured distance from the edge of the surface water body under high flow conditions (determined by the 100 year floodplain elevation boundary or floodway, as defined in Federal Emergency Management Agency flood hazard maps) to the wellhead. The ground water flow path to a horizontal well is the measured distance from the bed of the river under normal flow conditions to the closest horizontal well lateral.

These required flow path distances for Cryptosporidium treatment credit are based on pathogen and surrogate monitoring data from bank filtration field studies (Wang et al. 2001, Havelaar et al. 1995, Medema et al. 2000). Results from these studies show that significant removal of anaerobic and aerobic spores can occur during passage across the surface water—ground water interface, with lesser removal occurring during ground water transport within the aquifer away from that interface. The ground water—surface water interface is usually comprised of finer grained material that lines the bottom of the riverbed. Typically, the thickness of the interface is small, ranging from a few inches to a foot.

These results suggest that during normal and low surface water elevations, the surface water-ground water interface will perform effectively to remove microbial contamination like Cryptosporidium. During short periods of flooding, substantially lower removal rates may occur due to scouring of the riverbed and removal of the protective, fine-grained material. Assessing the mean Cryptosporidium removal that a bank filtration process will achieve over the period of a year requires consideration of both high and low removal periods. By considering all time intervals with differing removal rates over the period of a year, EPA concluded that 0.5-log removal over 25 feet and 1.0-log removal over 50 feet are appropriate estimates of the mean performance of a bank filtration process (USEPA 2003a).

Wells Must Be Continuously Monitored for Turbidity

Similar pathogen removal mechanisms are expected to occur in slow sand filtration and bank filtration. Under the 40 CFR 141.73(b)(1), the turbidity level of slow sand filtered water must be 1 NTU or less in 95 percent of the measurements taken each month. Turbidity sampling is required once every four hours, but may be reduced to once per day under certain conditions. Just as turbidity monitoring is used to provide assurance that the removal credit assigned to a slow sand filter is being realized, today's rule requires turbidity monitoring at least once every 4 hours for all bank filtration wells that receive treatment credit.

If monthly average turbidity levels (based on daily maximum values in the well) exceed 1 NTU, the PWS must report this result to the State and conduct an assessment to determine the cause of the high turbidity levels in the well. If the State determines that microbial removal has been compromised, the State may revoke treatment credit until the PWS implements corrective actions to remediate the problem.

Demonstration of Performance

EPA recognizes that some bank filtration processes may achieve mean Cryptosporidium removal greater than 1-log. Consequently, today's rule allows PWSs to receive greater than 1.0-log Cryptosporidium treatment credit for bank filtration through a State-approved demonstration of performance study. This allowance is a change from the proposed rule, which did not explicitly recognize demonstration of performance for bank filtration (USEPA 2003a). This change reflects EPA's agreement with public comment, described next, which recommended that EPA explicitly recognize the option to conduct a bank filtration performance study for greater than 1.0-log treatment credit.

A demonstration of performance study must involve the collection of data on the removal of Cryptosporidium or surrogates and related hydrogeologic and water quality parameters during the full range of operating conditions. PWSs must sample from both the production well(s) and one or more monitoring wells that are screened and located along the shortest flow path between the surface water and the production well(s). This will allow determination of the removal efficiency of the aquifer.

Because directly measuring Cryptosporidium removal will not be feasible for most PWSs, today's rule allows PWSs to sample for a State-approved indicator, such as aerobic bacterial endospores. Research has shown that aerobic spores can be very mobile in the subsurface environment (Pang et al. 1998), and data collected by Wang et al. (2001) indicate that aerobic spores are present in some surface waters in sufficient quantity to allow measurement of log removal values.

EPA has provided guidance on conducting site-specific bank filtration

studies in the Toolbox Guidance Manual. This guidance discusses data needs and analysis for a performance demonstration so that the State may tailor the study plan to meet site-specific hydrogeological and operational conditions.

In summary, EPA believes that full-scale field data support prescribed Cryptosporidium treatment credit up to 1.0-log for bank filtration under the required conditions for set-back distance, aquifer material, collection device type, and turbidity monitoring. Demonstration of performance provides an appropriate opportunity for States to award higher Cryptosporidium treatment credit for bank filtration on a site-specific basis.

For PWSs using bank filtration when they must conduct source water monitoring for bin classification, the required sampling locations reflect the intent for this monitoring to capture the level of Cryptosporidium entering a PWS's primary filtration treatment process. Where bank filtration serves as pretreatment to a filtration plant, PWSs must collect source water samples after bank filtration but prior to the filtration plant. In this case, the Cryptosporidium removal that bank filtration achieves will be reflected in the monitoring results and bin classification for the filtration plant. In contrast, where bank filtration is the primary filtration process, meaning that a PWS uses bank filtration to comply with the Cryptosporidium treatment requirements of the IESWTR or LT1ESWTR, PWSs must collect samples in the surface water source (e.g, the river).

c. Summary of Major Comments

Public comments on the August 11, 2003, LT2ESWTR proposal supported awarding Cryptosporidium treatment credit for bank filtration. Many commenters, however, stated that the proposed levels of credit (0.5- and 1.0-log) were insufficient. To address this issue, commenters supported allowing PWSs to obtain greater treatment credit by performing a site-specific study of bank filtration removal efficiency. Commenters recommended that site-specific bank filtration studies involve the measurement of surrogates for Cryptosporidium removal using monitoring wells located along the shortest flow path between the surface water and the production well.

EPA agrees that some bank filtration sites may achieve greater than 1.0-log Cryptosporidium removal. Today's rule establishes the proposed bank filtration Cryptosporidium treatment credits of 0.5- and 1.0-log and allows PWSs to apply to the State for higher levels of credit through a site-specific demonstration of performance. In such a study, PWSs must measure the removal of Cryptosporidium or a State-approved surrogate using monitoring wells located along the flow path, as recommended by commenters.

Some commenters cited research addressing appropriate surrogate organisms for estimating Cryptosporidium removal in surface water treatment plants and bank filtration sites. Commenters recommended that EPA recognize aerobic endospores as a surrogate measure in Cryptosporidium removal studies, including those for bank filtration.

EPA agrees that based on available information, aerobic spores are suitable Cryptosporidium removal surrogates for bank filtration processes due to their size, resistance to inactivation, and concentration in surface and ground waters. Data from several bank filtration sites on the use of aerobic spores as a Cryptosporidium removal surrogate are available. The Toolbox Guidance Manual identifies aerobic spores as suitable in conjunction with other hydrogeologic data for making site-specific determinations for additional Cryptosporidium removal credit.

In guidance, EPA suggests that where feasible, PWSs measure diatom species in conjunction with aerobic spores in bank filtration studies because Cryptosporidium oocysts are intermediate in size between the two surrogate groups. Further, EPA recognizes the current uncertainties and limitations in available information on surrogates for bank filtration and will update guidance as warranted by new information.

7. Combined Filter Performance

a. Today's Rule

For water treatment plants that use filtration, the turbidity of the filtered water is an indicator of how effectively the plant is removing particulate matter, including microbial pathogens, from the raw water. PWSs using conventional filtration treatment or direct filtration receive an additional 0.5-log Cryptosporidium treatment credit during any month the PWS meets the following standard:

- The turbidity level of representative samples of a PWS's filtered water (i.e., the combined filter effluent) is less than or equal to 0.15 NTU in at least 95 percent of the measurements taken each month. PWSs must continue to measure turbidity as specified in 40 CFR 141.74(a) and (c), which generally require sampling at least every four hours using approved methods.

PWSs using other types of filtration processes, including slow sand, diatomaceous earth, membranes, bag, or cartridge filtration, are not eligible for this treatment credit.

b. Background and Analysis

Turbidity is a method defined parameter that is based on measuring the amount of light scattered by suspended particles in a solution. This measure can detect the presence of a wide variety of particles in water, including microorganisms, but cannot provide specific information on particle type, number, or size. In filtered water, the turbidity level indicates how well the filtration and other upstream clarification processes have performed in removing particles from the raw water, with lower turbidity indicating better particle removal. Thus, lower filtered water turbidity is associated with a decreased likelihood that microbial pathogens like Cryptosporidium have passed through the filtration plant and into the water distributed to consumers.

Under existing regulations, PWSs that filter must monitor turbidity in the combined filter effluent (CFE) at least every four hours using approved methods, although States may reduce this frequency to once per day for PWSs serving 500 people or fewer (40 CFR 141.74(a) and (c)). For PWSs using conventional or direct filtration, at least 95 percent of the CFE turbidity measurements must be less than or equal to 0.3 NTU, and the turbidity must never exceed 1 NTU (40 CFR 141.173(a) and 141.551(a)–(b)).

The Stage 2 M–DBP Advisory Committee recommended an additional 0.5-log Cryptosporidium treatment credit for PWSs that achieve a CFE turbidity less than or equal to 0.15 NTU in at least 95 percent of measurements per month (USEPA 2000a). This 95th percentile turbidity standard is one half the level required under existing regulations for PWSs using conventional or direct filtration, as stated earlier. The August 11, 2003 proposal included this treatment credit for PWSs using conventional or direct filtration (USEPA 2003a), and EPA is establishing it in today's final rule with no changes from the proposal. The following discussion summarizes the basis for this treatment credit.

In the proposal, EPA analyzed the improvement in Cryptosporidium removal that conventional and direct filtration plants realize when operating at lower effluent turbidity levels. For this analysis, EPA estimated that PWSs

complying with the existing 95th percentile CFE turbidity standard of 0.3 NTU will typically operate with filter effluent turbidity between 0.1–0.2 NTU; PWSs complying with a CFE standard of 0.15 NTU were estimated to operate with filter effluent turbidity less than 0.1 NTU. Accordingly, EPA compared Cryptosporidium removal efficiencies when effluent turbidity was below 0.1 NTU with those when effluent turbidity was in the range of 0.1–0.2 NTU.

Studies by Patania et al. (1995), Emelko et al. (1999), and Dugan et al. (2001) observed the average removal of Cryptosporidium to be 0.5-to 1.2-log greater when filter effluent turbidity was less than 0.1 NTU in comparison to removal with effluent turbidity between 0.1–0.2 NTU. These studies, therefore, indicate that PWSs complying with a filter effluent turbidity standard of 0.15 NTU will achieve at least 0.5-log greater Cryptosporidium removal than PWSs complying with the existing 0.3 NTU standard. Based on this finding, EPA concluded that an additional 0.5-log Cryptosporidium treatment credit is appropriate for PWSs using conventional or direct filtration that meet a 95th percentile CFE turbidity standard of 0.15 NTU.

Other types of filtration processes, such as slow sand, diatomaceous earth, membranes, bag, or cartridge filtration, are not eligible for this treatment credit. These filtration processes remove Cryptosporidium through different mechanisms than those operative in rapid granular media filtration, which is used in conventional and direct filtration. Available data do not establish a similar relationship between lower filter effluent turbidity and improved Cryptosporidium removal efficiency for these other filtration processes.

The SAB reviewed the proposed additional Cryptosporidium treatment credit for PWSs that operate with very low filtered water turbidity. In their report, the SAB stated that further lowering of turbidity would result in further reductions in Cryptosporidium in the effluent from filtration processes, but available data were limited in showing the exact removal that can be achieved. Based on the data provided, the SAB recommended that no additional treatment credit be given to plants that demonstrate a CFE turbidity of 0.15 NTU or less (SAB 2003).

In addressing this SAB recommendation, EPA recognizes that precisely quantifying the increase in Cryptosporidium removal that a particular filtration plant will realize when operating at lower filter effluent turbidity is not generally feasible. Available data, though, consistently show that removal of Cryptosporidium is at least 0.5-log greater when filter effluent turbidity reflects compliance with a 0.15 NTU standard in comparison to a 0.3 NTU standard. Further, treatment plants operating at lower filter effluent turbidity will achieve increased removal of other microbial pathogens present in the raw water. In consideration of these factors, EPA believes that PWSs should receive an additional 0.5-log Cryptosporidium treatment credit when at least 95 percent of CFE turbidity measurements are less than or equal to 0.15 NTU.

Another key issue in establishing additional treatment credit based on low filtered water turbidity is the performance of analytical instruments (turbidimeters) to accurately measure turbidity at low levels. In the proposal, EPA reviewed studies of low level turbidity measurements by EPA (1998c), Sadar (1999), and Letterman et al. (2001). Among the significant findings of these studies are the following:

(1) On-line turbidimeters typically had a positive bias (i.e., a higher turbidity reading) in comparison to bench-top turbidimeters. EPA expects that most PWSs that receive additional treatment credit for low filter effluent turbidity will use on-line turbidimeters. This finding suggests that the error in turbidimeter readings may be generally conservative, so that PWSs will operate at lower than required turbidity levels.

(2) Different turbidimeters did not agree well when used to measure low level turbidity, which may be due to differences in instrument design. This finding suggests that low level turbidity measurements may be viewed as a relative indicator of water quality improvement at a particular PWS but may be less applicable for making comparisons among different PWSs.

In addition, the American Society for Testing and Materials (ASTM) has issued standard test methods for measurement of turbidity below 5 NTU by on-line (ASTM 2001) and static (ASTM 2003) instruments. These methods specify that the instrument should permit detection of turbidity differences of 0.01 NTU or less in waters having turbidities of less than 1.00 NTU (ASTM 2001) and 5.0 NTU (ASTM 2003), respectively.

After reviewing these studies and the ASTM methods, EPA concluded that currently available monitoring equipment can reliably measure turbidity at levels of 0.15 NTU and lower. Rigorous calibration and maintenance of turbidity monitoring equipment is necessary, however. EPA has developed guidance on proper calibration, operation, and maintenance of turbidimeters (USEPA 1999c).

c. Summary of Major Comments

Public comment on the August 11, 2003, LT2ESWTR proposal supported awarding additional Cryptosporidium treatment credit for PWSs that achieve lower filtered water turbidity. Commenters raised specific concerns with the criteria for PWSs to receive this credit, the available data that support this credit, and the performance of turbidimeters for measuring turbidity at very low levels. A summary of these comments and EPA's responses follows.

Most commenters supported awarding 0.5-log additional Cryptosporidium treatment credit for PWSs that achieve at least 95 percent of CFE turbidity measurements less than or equal to 0.15 NTU. A few commenters, however, recommended that PWSs only receive additional treatment credit for demonstrating this level of turbidity performance in each individual filter effluent (IFE), rather than the CFE. In addition, one commenter stated that PWSs should be required to monitor CFE turbidity every 15 minutes, rather than every four hours as required under current regulations.

In response, EPA agrees with the recommendation of most commenters and has established additional Cryptosporidium treatment credit based on meeting a 95th percentile turbidity level of 0.15 NTU in the CFE. EPA recognizes, however, that achieving low turbidity in each IFE may represent a higher level of performance than achieving low turbidity in the CFE. As described in the next section, EPA has also established standards for additional Cryptosporidium treatment credit based on low IFE turbidity in today's rule. EPA does not have data indicating that PWSs should monitor the CFE turbidity at a higher frequency than every four hours, as required under existing regulations. Consequently, EPA is not changing the frequency of required CFE turbidity monitoring as a condition for PWSs to receive additional treatment credit under today's rule.

One commenter summarized additional studies that provide data on the improvement in Cryptosporidium removal efficiency at lower filter effluent turbidity levels. According to this commenter, these studies demonstrate that lowering filter effluent turbidity from 0.3 to 0.15 NTU translates to an improvement in Cryptosporidium removal of more than 1.5-log, with individual studies showing a range of >0.7-log to >3-log based on median removal. EPA finds that these studies bolster the conclusion that PWSs operating to meet 0.15 NTU in the filter effluent will achieve at least 0.5-

log greater Cryptosporidium removal than PWSs operating to meet 0.3 NTU. Thus, they support the additional 0.5-log Cryptosporidium treatment credit under today's rule for PWSs meeting 0.15 NTU at the 95th percentile in the CFE.

In regard to the measurement of low level turbidity, some commenters raised concerns that turbidimeters used by the U.S. water supply industry do not agree when used to measure turbidity in the 0.01 to 0.5 NTU range. Further, these differences are independent of the calibration method used and can be significant when comparing instruments by different manufacturers. Other commenters stated that turbidimeters can accurately reflect turbidity values less than 0.15 NTU if properly calibrated, and some commenters cited the ASTM method development process to support this assessment. In addition, commenters suggested that available guidance on turbidity measurement provides quality assurance measure that can reduce analytical uncertainty.

EPA agrees with commenters that available methods and instruments are adequate to demonstrate compliance with a 0.15 NTU turbidity level. In particular, EPA believes that monitoring low level turbidity can be effective for demonstrating water quality improvements at individual plants, but also recognizes that the performance of turbidimeters used at different plants may vary. Further, calibration and maintenance of turbidity monitoring equipment is critical, and EPA has developed guidance on these procedures (USEPA 1999c).

8. Individual Filter Performance

a. Today's Rule

PWSs using conventional filtration treatment or direct filtration receive an additional 0.5-log Cryptosporidium treatment credit during any month the PWS meets the following criteria:

- The filtered water turbidity for each individual filter is less than or equal to 0.15 NTU in at least 95 percent of the measurements recorded each month; and
- No individual filter has a measured turbidity level greater than 0.3 NTU in two consecutive measurements taken 15 minutes apart.

PWSs must continue to monitor turbidity for each individual filter continuously and record the results every 15 minutes, as required under 40 CFR 141.174 and 141.560.

PWSs that receive this 0.5-log Cryptosporidium treatment credit for individual filter performance also receive 0.5-log treatment credit for combined filter performance, as described in section IV.D.7, for a total additional treatment credit of 1.0-log. Conversely, PWSs are not required to pursue individual filter performance credit to remain eligible for combined filter performance credit.

If a PWS has received credit for individual filter performance to comply with its Cryptosporidium treatment requirements and fails to meet the required criteria for this credit during any month, the PWS will not incur a treatment technique violation if the State determines the following:

- The failure to meet the required criteria for individual filter performance treatment credit was due to unusual and short-term circumstances that could not reasonably be prevented through optimizing treatment plant design, operation, and maintenance; and
- The PWS has experienced no more than two such failures in any calendar year.

This treatment credit is not applicable to other types of filtration processes, including slow sand, diatomaceous earth, membranes, bag, or cartridge filtration.

b. Background and Analysis

Awarding additional treatment credit for individual filter performance is based on the expectation that achieving low filtered water turbidity in each individual filter will provide increased protection against microbial pathogens. Most treatment plants have multiple filters. Moderately elevated turbidity in the effluent from a single filter may not significantly affect the turbidity of the combined filter effluent, but may indicate a reduction in the overall pathogen removal efficiency of the filtration process. Consequently, a primary goal in optimizing water treatment plant performance is ensuring that each filter always produces very low turbidity water.

The criteria for PWSs to achieve the additional 1.0-log Cryptosporidium treatment credit for individual filter performance reflect goals of Phase IV of the Partnership for Safe Water (Partnership). The Partnership is a voluntary cooperative program involving PWSs, professional associations, and Federal and State regulatory agencies that seeks to increase protection against microbial contaminants by optimizing water treatment plant performance. The Stage 2 M–DBP Advisory Committee recommended 1.0-log treatment credit for PWSs that successfully participate in a peer review program and identified Phase IV of the Partnership as a program where such credit would be appropriate (USEPA 2000a).

At the time of the Advisory Committee recommendation, the performance goals for Phase IV of the Partnership reflected those of the EPA Composite Correction Program (USEPA 1991a) and involved an on-site evaluation by a third-party team. Phase IV performance goals for individual filters included filtered water turbidity less than 0.1 NTU at least 95 percent of the time based on daily maximum values and a maximum measurement of 0.3 NTU. The purpose of the on-site evaluation was to confirm that a PWS had met Phase IV performance goals or had achieved the highest level of performance given its unique raw water quality.

After the Stage 2 M–DBP Agreement in Principle was signed in September 2000, the Partnership eliminated on-site third-party evaluation as a component of Phase IV. Instead, Phase IV required completion of an Optimization Assessment Spreadsheet in which the PWS entered water treatment data to demonstrate that it had achieved Phase IV performance levels. The application also required narratives related to the administrative support and operational capabilities necessary to sustain performance long-term.

The August 11, 2003 LT2ESWTR proposal included a 1.0-log Cryptosporidium treatment credit for PWSs that met the individual filter performance goals of Phase IV of the Partnership (i.e., 95 percent of daily maximum values below 0.1 and no values above 0.3 NTU) (USEPA 2003a). Rather than requiring an application package with historical data and narratives, however, the proposed rule required PWSs to report filter effluent turbidity data to the State each month to demonstrate compliance with these filter performance goals.

The Partnership modified the Phase IV goals for individual filter performance in 2003. A revised goal is filtered water turbidity less than 0.10 NTU at least 95 percent of the time based on values recorded at 15 minute time intervals. Thus, where the earlier goal was based on daily maximum values for each filter, the revised goal is based on all values for each filter—a less stringent approach. The Partnership made this modification after finding that none of the water treatment plants that had been evaluated could consistently meet the 0.1 NTU goal using daily maximum values and, further, that this goal was biased against plants with more filters.

In today's final rule, EPA has adjusted the criteria from the proposal for PWSs

to receive additional treatment credit based on individual filter effluent turbidity. These adjustments are in response to the changes the Partnership made to Phase IV individual filter performance goals. Under today's rule, PWSs receive 1.0-log additional Cryptosporidium treatment credit if effluent turbidity from each filter is less than or equal to 0.15 NTU at least 95 percent of the time and never exceeds 0.3 NTU in two consecutive measurements taken 15 minutes apart.

EPA expects that PWSs will operate at less than 0.1 NTU in order to comply with a regulatory limit of 0.15 NTU. Further, EPA believes that assessing individual filter compliance with a maximum turbidity level of 0.3 NTU based on two consecutive measurements taken 15 minutes apart is appropriate. This approach allows for brief fluctuations in turbidimeter readings that may not indicate a degradation in filtered water quality to occur without penalizing a PWS, but it should catch filters that significantly exceed 0.3 NTU over the course of a month. EPA applied this approach to individual filter monitoring under the IESWTR and LT1ESWTR. Consequently, EPA regards these criteria as comparable to the revised Partnership Phase IV standards for individual filter performance.

In addition, today's rule gives States authority to determine whether to issue a treatment technique violation for PWSs that exceed individual filter performance limits. This authority applies in the case where a PWS receives credit for individual filter performance to meet the treatment requirements of today's rule and fails to achieve the criteria to receive this credit during a month. If the State determines that this failure was due to unusual and short-term circumstances that could not reasonably be prevented through treatment optimization, the State may choose not to issue a treatment technique violation, which the PWS otherwise will incur. Because this authority should be applied only to unusual plant circumstances, a State cannot make this determination if a PWS has experienced more than two such failures in any calendar year.

EPA is granting States this authority because PWSs that consistently meet the criteria for individual filter performance treatment credit may occasionally experience short-term deviations from these criteria due to circumstances largely beyond the PWS's control. An example of such a circumstance may be malfunctioning equipment that a PWS quickly removes from service, but that nevertheless prevents the PWS from fully meeting individual filter performance criteria in a particular month. EPA believes that States should only apply this authority in cases where PWSs have consistently achieved the criteria for individual filter performance treatment credit in previous months.

The approach in today's final rule for valuing individual filter performance treatment credit differs from the approach in the proposal. EPA's intent in both the proposal and today's rule is to award an additional 1.0-log Cryptosporidium treatment credit to PWSs that meet the criteria for individual filter performance. In the proposal, however, PWSs could receive 1.0-log additional treatment credit specifically for meeting the individual filter performance criteria, but were then not eligible to receive any treatment credit under the combined filter performance option. In today's rule, PWSs receive 0.5-log credit for the individual filter performance option and also receive an additional 0.5-log treatment credit for the combined filter performance option (discussed in section IV.D.7), resulting in 1.0-log total additional credit. EPA has made this modification so that if a PWS fails in an attempt to achieve individual filter performance credit, the PWS is clearly still eligible to received combined filter performance credit.

In a review of a draft LT2ESWTR proposal, the SAB recommended that PWSs receive 0.5-log, rather than 1.0-log, additional Cryptosporidium treatment credit for achieving individual filter effluent turbidity below 0.15 NTU at the 95th percentile (SAB 2003). In response to this SAB recommendation, today's rule requires additional individual filter performance criteria to support 1.0-log total additional treatment credit. Specifically, today's rule incorporates the Partnership Phase IV performance goal that individual filter effluent turbidity never exceed 0.3 NTU (as described earlier, EPA concluded that determining compliance with this standard based on two consecutive measurements taken 15 minutes is appropriate and consistent with existing regulations). Thus, EPA believes that these criteria, in conjunction with the expectation that controlling effluent turbidity at all filters individually rather than just the combined filter effluent will generally result in lower microbial risk, justify 1.0-log additional treatment credit.

c. Summary of Major Comments

Public comment on additional treatment credit for individual filter performance in the August 11, 2003 proposal raised a number of issues: changes in the Partnership Phase IV criteria and achievability of the proposed criteria for this credit, credit for participating in peer review programs, and a review process for data that exceed regulatory limit. A summary of these comments and EPA's responses follows.

Several commenters stated that PWSs could not consistently achieve the proposed individual filter effluent turbidity criterion of 95 percent of daily maximum measurements less than or equal to 0.1 NTU. Commenters provided data on turbidity levels in PWSs to support this assertion and indicated that the Partnership modified this criterion in the Phase IV individual filter performance goals because PWSs could not meet it. Alternatives recommended by commenters for the final rule included the use of the revised Partnership Phase IV goals for individual filter effluent turbidity or a more stringent criterion for combined filter effluent turbidity.

In response, EPA agrees that current Partnership Phase IV goals provide appropriate criteria for awarding 1.0-log total additional Cryptosporidium treatment credit. Today's rule grants this total credit to PWSs that meet a 95th percentile individual filter effluent turbidity limit of 0.15 NTU, and EPA expects that PWSs complying with this limit will operate under the Partnership goal of 0.10 NTU. EPA does not support awarding a higher level of additional treatment credit for a more stringent combined filter effluent turbidity criterion, beyond the 0.5-log credit available under combined filter performance (see section IV.D.7). The purpose of the individual filter performance toolbox option is to recognize the higher pathogen removal PWSs will likely achieve by maintaining very low effluent turbidity for each individual filter.

A few commenters suggested that as an alternative to establishing numerical criteria for individual filter performance, today's rule should award additional treatment credit for PWSs that successfully participate in a peer review program. In addition to the Partnership, commenters listed the Area Wide Optimization Program and the Texas Optimization Program as examples of programs that will provide for comprehensive improvements in treatment performance.

EPA agrees that participation in peer review programs is beneficial for PWSs. Further, such programs may assist PWSs in meeting the filtration performance criteria in today's rule for additional Cryptosporidium treatment credit. EPA does not believe, however, that mere participation in a peer review program

is an appropriate basis for awarding additional treatment credit. Rather, to ensure national consistency in standards for compliance with treatment requirements, EPA has concluded that additional treatment credit should be based on PWSs meeting specified criteria for enhanced treatment performance.

Another significant issue raised by commenters is the need for a review process for deviations from the criteria for individual filter performance due to circumstances that cannot be prevented through plant optimization. An example given by several commenters is a filter that malfunctions and is taken out of service, but that may have exceeded the individual filter performance turbidity criteria for a short period when the filter was operating.

EPA agrees that circumstances may occur that are beyond the PWS's control and that prevent the PWS from fully meeting the criteria for individual filter performance in a particular month. If a PWS relies on individual filter performance treatment credit to meet the treatment requirements of today's rule and the PWS fails to meet all criteria for this credit in a given month, the State may review the reasons for this failure. If the State finds that the failure was due to circumstances that could not be prevented through plant optimization, the State may choose not to issue a treatment technique violation on up to two such occasions in a calendar year.

9. Demonstration of Performance

a. Today's Rule

A demonstration of performance is a site-specific test that assesses the Cryptosporidium removal efficiency of a water treatment plant or a treatment process within a plant. Under today's rule, PWSs may undertake demonstration of performance testing for the following purposes:

(1) To establish a Cryptosporidium treatment credit that is higher than the prescribed treatment credit in today's rule for a water treatment plant or a treatment process in the microbial toolbox; or

(2) To establish a Cryptosporidium treatment credit for a treatment process that is not included in the microbial toolbox or that does not meet the design or operational criteria for prescribed treatment credit in the microbial toolbox.

The specific requirements that apply to demonstration of performance testing are as follows:

- PWSs may receive Cryptosporidium treatment credit for a water treatment plant or a treatment process within a plant that is based on a site-specific demonstration of Cryptosporidium removal efficiency. This demonstration of performance treatment credit may be greater than or less than any prescribed treatment credit in today's rule.
- The site-specific demonstration of Cryptosporidium removal efficiency must follow a State-approved protocol and may involve the use of surrogates rather than Cryptosporidium.
- The State must approve through written notification any treatment credit based on a demonstration of performance. As a condition of approval, the State may designate monitoring and treatment performance criteria the PWS must meet and report on an ongoing basis to remain eligible for the credit. The State may designate such criteria to verify that the PWS maintains the operating conditions under which the State approved the demonstration of performance treatment credit.
- PWSs are not eligible for prescribed treatment credit for any treatment process that is included in a demonstration of performance credit.

b. Background and Analysis

The prescribed Cryptosporidium treatment credits in today's rule for water treatment plants and for treatment processes in the microbial toolbox are based on conservative estimates of mean Cryptosporidium removal efficiencies. Due to site-specific conditions, however, some PWSs will achieve greater Cryptosporidium removal than reflected in the prescribed treatment credits. In addition, some PWSs will have treatment processes that are not included in the microbial toolbox or that do not meet microbial toolbox criteria for prescribed treatment credit. In all these cases, PWSs have the option to undertake demonstration of performance testing to establish an appropriate level of Cryptosporidium treatment credit for the treatment plant or treatment process.

The option for demonstration of performance testing in today's rule reflects a recommendation by the Stage 2 M–DBP Advisory Committee. Specifically, the Committee stated that the LT2ESWTR should allow site-specific testing both to establish Cryptosporidium treatment credit above the prescribed credit for microbial toolbox processes and to demonstrate Cryptosporidium removal for technologies not listed in the microbial toolbox. The August 11, 2003 LT2ESWTR proposal included the demonstration of performance option (USEPA 2003a), and EPA is establishing it in today's final rule.

Demonstration of performance testing will be specific to a particular site and will depend on the treatment processes being tested, water quality, plant infrastructure, PWS resources, and other factors. Consequently, today's rule does not establish specific protocols for demonstration of performance testing. Rather, today's rule gives States the authority to approve testing protocols developed by PWSs and to determine what level of Cryptosporidium treatment credit is appropriate. The Toolbox Guidance Manual provides recommendations to PWSs and States on conducting demonstration of performance testing, including analytical methods for measuring aerobic and anaerobic spores.

In general, demonstration of performance testing should encompass the full range of expected operating conditions and should conservatively assess the degree of Cryptosporidium removal that a treatment process can reliably achieve. Directly quantifying the removal of Cryptosporidium typically is not feasible in full-scale testing due to limitations in source water concentrations and analytical method performance. Consequently, demonstration of performance testing that is conducted at full-scale may involve the use of surrogates, such as aerobic spores, that have been shown to correlate with the removal of Cryptosporidium. PWSs and States may also consider the use of pilot-scale studies in conjunction with full-scale studies for demonstration of performance testing.

As a condition of approving a demonstration of performance credit, the State may designate treatment performance criteria the PWS must meet on an ongoing basis to remain eligible for the credit. For example, if a PWS conducts a demonstration of performance study while operating with very low filtered water turbidity, the State may establish as a condition of approving treatment credit based on the study that the PWS must continue operating at the low filtered water turbidity. EPA believes this condition is necessary because, in this example, if the PWS were to begin operating at a higher filtered water turbidity level, the demonstration of performance study results might no longer represent the PWSs actual performance.

PWSs are not eligible for prescribed treatment credit for any treatment process that is included in a demonstration of performance credit. For example, if a PWS receives a demonstration of performance treatment credit of 4-log for Cryptosporidium removal through a conventional treatment plant (i.e., coagulation/sedimentation/filtration), the PWS is not

also eligible for additional treatment credit for combined filter performance. In this case, the demonstration of performance testing accounts for the removal achieved by filtration.

c. Summary of Major Comments

Public comment on the August 11, 2003 LT2ESWTR proposed supported inclusion of the demonstration of performance option to award site-specific treatment credit to PWSs. Commenters stated that many well-run surface water treatment plants achieve significantly greater Cryptosporidium removal than the prescribed treatment credit, and demonstration of performance testing is needed to award an appropriate level of credit in such cases. Two aspects of this option that received significant public comment are the provision for States to award less than the prescribed treatment credit if indicated by testing results and the need for guidance on demonstration of performance testing. These comments and EPA's responses are summarized as follows.

Several commenters recommended that EPA eliminate the provision that allows States to award less than the prescribed treatment credit based on demonstration of performance testing. These commenters stated that pilot- and full-scale testing is conservative and challenging to implement and that for past regulations, States generally have not awarded lower treatment credit based on a site-specific study. If this provision remains in the regulation, commenters suggested that EPA provide criteria addressing how it should be applied. Such criteria should recognize the conservative nature of testing with surrogates for Cryptosporidium removal and the potential for misleading or flawed testing results.

In response, EPA believes that States should have the discretion to award either more or less treatment credit than the prescribed credit on a case-by-case basis where a State has site-specific information that an alternative credit is appropriate. Today's rule allows this. EPA recognizes, however, that demonstration of performance testing should be designed to provide a conservative estimate of treatment efficiency and, as such, is not generally intended to reduce the level of treatment credit a PWS receives. Further, results from demonstration of performance testing should be rigorously evaluated for flaws and bias prior to being used to support either a higher or lower treatment credit. The Toolbox Guidance Manual identifies approaches States may wish to consider in awarding higher or lower treatment credit.

Many commenters stated that EPA should provide thorough guidance on demonstration of performance testing. Topics for this guidance suggested by commenters include approaches to demonstrating treatment credit, minimum duration of testing, the use of safety factors, and periodic reconfirmation of testing results. Some commenters recommended that guidance address both full-scale testing with surrogates like aerobic spores and pilot-scale testing with Cryptosporidium or surrogates. Other commenters recommended that testing should be limited to full-scale processes and that testing with pilot-scale representations of full-scale equipment should be discouraged.

In the Toolbox Guidance Manual, EPA provides direction on procedures for demonstration of performance testing that addresses issues raised by commenters. These issues include surrogates for full-scale testing, potential roles for pilot-scale testing in conjunction with full-scale testing, minimum duration of testing to capture the full range of operating conditions, the analysis of data from testing to establish treatment credit, and routine monitoring to verify that the conditions under which demonstration of performance credit is awarded are maintained during routine operation. EPA believes that this guidance will assist PWSs and States with implementing demonstration of performance testing appropriately.

10. Bag and Cartridge Filtration

a. Today's Rule

Under today's rule, PWSs may receive Cryptosporidium treatment credit of up to 2.0-log for an individual bag or cartridge filter and up to 2.5-log for two or more bag or cartridge filters operated in series. To be eligible for this treatment credit, filters must meet the definition of a bag or cartridge filter and must undergo challenge testing to demonstrate removal efficiency with an applied safety factor, as described in this section.

Today's rule defines bag and cartridge filters as pressure driven separation processes that remove particulate matter larger than 1 micrometer using an engineered porous filtration media through either surface or depth filtration. Bag filters are constructed of a non-rigid, fabric filtration media housed in a pressure vessel in which the direction of flow is from the inside of the bag to the outside. Cartridge filters are typically constructed as rigid or semi-rigid, self-supporting filter elements housed in a pressure vessel in which flow is from the outside of the cartridge to the inside.

Today's rule treats bag and cartridge filters equivalently, with the following exception: If a cartridge filter meets the definition of a membrane filtration process and can be direct integrity tested according to the criteria specified in section IV.D.11, a PWS has the option to seek greater treatment credit for the filter as a membrane. Section IV.D.11 describes criteria for awarding treatment credit to membranes.

Today's rule requires challenge testing to establish Cryptosporidium treatment credit for bag and cartridge filters. This challenge testing is product-specific and not site-specific. Once challenge testing is performed on a specific bag or cartridge filtration product, PWSs that install the specific filtration product are not required to repeat challenge testing at individual sites. For a PWS to receive Cryptosporidium treatment credit for a bag or cartridge filter, challenge testing must meet the following criteria:

- Challenge testing must be conducted on full-scale filters that match the filters the PWS will use in materials, construction, and associated housing or pressure vessel. If treatment credit will be based on filters operated in series then challenge testing must be performed on the filters in series.
- Challenge testing must involve measuring the removal by the filter of either Cryptosporidium or a surrogate that is removed no more efficiently than Cryptosporidium (i.e., the ''challenge particulate'').
- The analytical method used to measure removal in the challenge test must discretely quantify the specific challenge particulate. The maximum allowable feed water concentration of the challenge particulate used during a challenge test is 10,000 times the analytical method detection limit of the challenge particulate in the filtrate.
- During challenge testing, filters must be operated at the maximum design flow rate and for a duration sufficient to reach the maximum design pressure drop (i.e., ''terminal pressure drop''). PWSs may not operate bag or cartridge filters outside of these design parameters during routine use. In order to achieve terminal pressure drop during challenge testing, adding particulate matter, such as fine carbon test dust or bentonite clay particles, to the test water is allowed and may be necessary.
- In each challenge test, the removal of the challenge particulate must be measured during three periods over the

filtration cycle: (1) Within two hours of start-up of a new filter, (2) when the pressure drop is between 45 and 55 percent of the terminal pressure drop, and (3) when the pressure drop has reached 100 percent of the terminal pressure drop. A log removal value (LRV) must be calculated for each of these periods as follows: LOG_{10} (filter influent challenge particulate level) − LOG_{10} (filter effluent challenge particulate level). For each filter tested, the LRV for the filter (LRV_{filter}) is equal to the minimum of these three LRVs.

- The LRV_{filter} values for each filter that is tested are used to determine the removal efficiency that is assigned to the specific bag or cartridge filter product (*i.e.*, a filter product line) or combination of filters in series. If fewer than twenty filters are tested, the removal efficiency of the filter product line is equal to the lowest LRV_{filter} among the filters tested (today's rule does not specify a minimum number of filters to test). If twenty or more filters are tested, the removal efficiency of the filter product line is equal to the 10th percentile of the LRV_{filter} values among the filters tested.
- The Cryptosporidium treatment credit assigned to an individual bag or cartridge filter is equal to the removal efficiency established during challenge testing minus a 1.0-log factor of safety, up to a maximum treatment credit of 2.0-log (*e.g.*, if challenge testing demonstrates a removal efficiency of 3.0-log or greater, the filter is eligible to receive 2.0-log Cryptosporidium treatment credit).
- The Cryptosporidium treatment credit assigned to configurations of two or more bag or cartridge filters operated in series is equal to the removal efficiency established during challenge testing minus a 0.5-log factor of safety, up to a maximum treatment credit of 2.5-log (*e.g.*, if challenge testing demonstrates a removal efficiency of 3-log or greater, the filter receives 2.5-log Cryptosporidium treatment credit).

If a previously tested bag or cartridge filter is modified in a manner that could change the removal efficiency of the filter product line, a new removal efficiency must be established for the modified filter through challenge testing. If approved by the State, data from challenge testing conducted prior to promulgation of today's rule may be considered in lieu of additional testing. However, the prior testing must have been conducted in a manner that demonstrates a removal efficiency for Cryptosporidium commensurate with the treatment credit awarded to the filter.

b. Background and Analysis

Bag and cartridge filters are widely used by very small PWSs and in point-of-entry applications to remove particulate material from raw water, including microbial pathogens like Cryptosporidium. Depending on water quality and treatment plant infrastructure, these filters may be used as the sole filtration step or as a polishing filter that follows primary filtration processes. A critical aspect of bag and cartridge filters as defined in today's rule is that they cannot undergo direct integrity testing, which is used to detect leaks that could result in contamination of the treated water. Cartridge filters that meet the definition of a membrane process and can be direct integrity tested are considered membranes under today's rule, and these are described in section IV.D.11.

The Stage 2 M–DBP Advisory Committee recommended Cryptosporidium treatment credits of 1.0- and 2.0-log for bag and cartridge filters, respectively (USEPA 2000a), and the August 11, 2003 LT2ESWTR proposal included criteria for PWSs to receive these treatment credits. The proposed criteria required challenge testing and the application of a 1.0-log factor of safety to establish treatment credit. In today's final rule, EPA has modified these criteria to allow both bag and cartridge filters to be eligible for 2.0-log credit and to allow 2.5-log credit with a 0.5-log factor of safety for bag or cartridge filters operated in series. The following discussion summarizes the basis for these criteria and for differences between the proposal and today's final rule.

In the proposal, EPA reviewed bag and cartridge filtration studies by Long (1983), Schaub *et al.* (1993), Goodrich *et al.* (1995), Ciardelli (1996a and 1996b), Li *et al.* (1997), Roessler (1998), Enriquez *et al.* (1999), NSF (2001a and 2001b), and Cornwell and LeChevallier (2002). Results from these studies indicated that both bag and cartridge filters exhibit variable removal efficiency, ranging from 0.5- to 3.6-log. No correlation between the pore size rating established by the manufacturer and the removal efficiency of the filter was apparent. Additionally, available data did not indicate a strong relationship between commonly used process monitoring parameters, such as turbidity and pressure drop, and Cryptosporidium removal efficiency.

Due to this lack of correlation between either design criteria or process monitoring and removal efficiency, today's rule requires challenge testing of filters to establish Cryptosporidium treatment credit. Challenge testing must measure the removal across the filter of Cryptosporidium or a surrogate, like polystyrene microspheres, that is removed no more efficiently than Cryptosporidium (Long 1983, Li *et al.* 1997, NSF 2002b). Further, because studies have shown the removal efficiency of some bag and cartridge filters to decrease over the course of a filtration cycle (Li *et al.* 1997, NSF 2001a,b), challenge testing must assess removal efficiency during three periods: within two hours of startup of a new filter, between 45–55 percent of terminal pressure drop, and at the end of the run after terminal pressure drop is realized.

Bag and cartridge filter challenge testing is product-specific and not site-specific since the intent of this testing is to demonstrate the removal capabilities of the filtration device rather than evaluate the feasibility of implementing the technology at a specific plant. Challenge testing must be conducted using full-scale filter elements to assess the performance of the entire unit, including the filtration media, seals, filter housing and other components integral to the filtration system. To be eligible for treatment credit when operated in series, filters must be tested in series. Multiple filters of the same type can be tested to provide a better statistical basis for estimating removal efficiency. The Toolbox Guidance Manual provides information on bag and cartridge filter challenge testing.

Today's rule establishes the proposed requirement that a 1.0-log factor of safety be applied to the removal efficiency established during challenge testing for individual bag or cartridge filters when determining treatment credit. Thus, to receive a 2.0-log treatment credit, a removal efficiency of at least 3.0-log must be demonstrated during challenge testing. EPA believes that this factor of safety is necessary because integrity testing with bag and cartridge filters is not possible (note: under today's rule, cartridge filters that can be integrity tested are classified as membranes and no safety factor is required; see section IV.D.11).

Challenge testing provides an estimate of the removal efficiency of a bag or cartridge filter product line but does not involve testing every filter. Further, it does not fully capture the variation in filter performance that will occur over time during routine use. For membranes, the use of direct integrity tests, such as a pressure hold test, that is correlated to removal efficiency addresses this problem. With bag and cartridge filters, however, EPA is aware

of no equivalent test, and parameters like turbidity and pressure differential that may be monitored with these filters have not been shown to correlate with Cryptosporidium removal efficiency. Consequently, a safety factor is necessary to account for variation in individual filter performance relative to challenge test results.

Individual bag and cartridge filters are eligible for a maximum Cryptosporidium treatment credit of 2.0-log. EPA proposed this level of credit for cartridge filters but proposed a 1.0-log maximum credit for bag filters, as recommended by the Advisory Committee. However, after further reviewing available data, EPA has concluded that treatment studies do not support establishing different limits on treatment credit for bag and cartridge filters. Accordingly, today's rule treats bag and cartridge filters equivalently. EPA continues to believe that 2.0-log is an appropriate maximum treatment credit for a single bag or cartridge filter, based on available data on the removal of Cryptosporidium and surrogates by these processes and the absence of a direct integrity test.

Today's rule also establishes criteria for awarding treatment credit to bag or cartridge filters operated in series. EPA believes that the use of these filters in series provides clear advantages in comparison to operation of a single filter. Series operation will achieve both greater removal efficiency and improved reliability by lessening the impact of variation in the performance of a single filter. In consideration of these factors, bag or cartridge filters operated in series are eligible for a higher Cryptosporidium treatment credit of 2.5-log and require a lower safety factor of 0.5-log applied to challenge test results when determining treatment credit.

c. Summary of Major Comments

In response to the August 11, 2003 proposal, EPA received significant public comment on the following issues related to bag and cartridge filtration: the allowable treatment credit, the factor of safety applied to challenge testing results to determine treatment credit, and the procedure for determining the removal efficiency. A summary of these comments and EPA's responses follows.

In regard to the proposed treatment credits, several commenters recommended that bag and cartridge filters should be eligible for up to 2.0- and 2.5-log credit, respectively, if supported by the challenge test results. Others commented that filters should be allowed to qualify for removal credits at or below the 1.0- and 2.0-log credits in the proposal. EPA agrees that additional flexibility should be provided with respect to the removal credit awarded to bag and cartridge filters. After reviewing these comments and reassessing data presented in the proposal on the removal efficiencies of bag and cartridge filters, EPA revised the proposal to allow up to 2.0-log treatment credit for either a single bag or cartridge filter. In addition, today's rule allows up to 2.5-log credit for bag or cartridge filters operated in series.

With respect to the 1.0-log safety factor applied to challenge test results to determine treatment credit, some commenters supported this approach, while others recommended a reduced safety factor. In response, EPA continues to believe that a 1.0-log safety factor is appropriate to address variability in individual filter performance and in the absence of a direct integrity test for bag and cartridge filters. Where filters are operated in series, however, EPA agrees that the safety factor should be reduced. Series operation provides an intrinsic process safety and will dampen some of the variability in removal efficiency observed for individual filters. Thus, EPA is reducing the factor of safety to 0.5-log for configurations consisting of two or more filters in series.

Commenters requested that EPA clarify the procedure used to determine the removal efficiency of bag and cartridge filters. In response, expanded and clarified guidance on conducting challenge tests to determine removal efficiency for bag and cartridge filters has been included in the Toolbox Guidance Manual.

11. Membrane Filtration

a. Today's Rule

Today's final rule establishes criteria for awarding Cryptosporidium treatment credit to membrane filtration processes. To receive removal credit, filters must meet the definition of a membrane filtration process and undergo challenge testing to establish removal efficiency; PWSs must periodically verify system integrity through direct integrity testing and perform continuous indirect integrity monitoring during use. The removal credit awarded to a membrane process is based on the removal efficiency demonstrated during challenge testing and the sensitivity of the direct integrity test.

For the purpose of today's rule, membrane filtration is defined as a pressure or vacuum driven separation process in which particulate matter larger than 1 micrometer is rejected by an engineered barrier, primarily through a size-exclusion mechanism, and which has a measurable removal efficiency of a target organism that can be verified through the application of a direct integrity test.

Membrane Challenge Testing

Any membrane filter used to meet the treatment requirements of today's rule must undergo challenge testing to determine its Cryptosporidium removal efficiency. Challenge testing establishes the maximum Cryptosporidium treatment credit a membrane filtration process is eligible to receive, provided this value is less than or equal to the sensitivity of the direct integrity test, as described later in this section. Challenge testing for membranes is product-specific, and PWSs that install membranes that have successfully undergone challenge testing are not required to repeat testing at their sites. Membrane challenge testing must meet the following criteria:

- Challenge testing must be conducted on either an identical full-scale module or a smaller-scale module identical in material and similar in construction to the membrane modules the PWS will use. A module is the smallest component of a membrane unit in which a specific membrane surface area is housed in a device with a filtrate outlet structure.
- Either Cryptosporidium or a surrogate that is removed no more efficiently than Cryptosporidium must be used as the challenge particulate during challenge testing.
- The analytical method used to measure removal in the challenge test must discretely quantify the specific challenge particulate. The maximum allowable feed water concentration used during a challenge test is 6.5-log (3.16×10^6) times the detection limit of the challenge particulate in the filtrate.
- Challenge testing must be conducted under representative hydraulic conditions at the maximum design flux and maximum design process recovery as specified by the manufacturer for the membrane filtration process. Flux is defined as the throughput of a pressure driven membrane process expressed as flow per unit of membrane area. Recovery is defined as the volumetric percent of feed water that is converted to filtrate over the course of an operating cycle uninterrupted by events such as chemical cleaning or a solids removal process (*i.e.*, backwashing).
- The removal efficiency for the membrane is determined from the results of the challenge test, expressed as a log removal value (LRV). A LRV must be calculated for each membrane module evaluated during the challenge

test based on the feed and filtrate concentrations of the challenge particulate for that module. The individual LRVs for each module are used to determine the overall removal efficiency of the membrane product. If fewer than twenty modules are tested, the overall removal efficiency is assigned a value equal to the lowest of the representative LRVs for the various modules tested. If twenty or more modules are tested, then the overall removal efficiency is assigned a value equal to the 10th percentile of the representative LRVs for the various modules tested.

• As part of the challenge test, a quality control release value (QCRV) must be established for a non-destructive performance test (*e.g.*, bubble point test, diffusive airflow test, pressure/vacuum decay test) that demonstrates the Cryptosporidium removal capability of the membrane module. The non-destructive performance test must be applied to each membrane module a PWS uses in order to verify Cryptosporidium removal capability. Membrane modules that do not meet the established QCRV are not eligible for the Cryptosporidium removal credit demonstrated during challenge testing.

If a previously tested membrane product is modified in a manner that could change the removal efficiency of the membrane or the applicability of non-destructive performance test and associated QCRV, the modified membrane filter must be challenge tested to establish the removal efficiency and QCRV. If approved by the State, data from challenge testing conducted prior to promulgation of today's rule may be considered in lieu of additional testing. However, the prior testing must have been conducted in a manner that demonstrates a removal efficiency for Cryptosporidium commensurate with the treatment credit awarded to the filter.

Membrane Direct Integrity Testing

In order to receive Cryptosporidium treatment credit for a membrane filtration process, PWSs must conduct direct integrity testing in a manner that demonstrates a removal efficiency equal to or greater than the removal credit awarded to the membrane filtration process. A direct integrity test is defined as a physical test applied to a membrane unit in order to identify and isolate integrity breaches (*i.e.*, one or more leaks that could result in contamination of the filtrate).

Each membrane unit must be independently direct integrity tested, where a membrane unit is defined as a group of membrane modules that share common valving which allows the unit to be isolated from the rest of the system for the purpose of integrity testing or other maintenance. The direct integrity test must be applied to the physical elements of the entire membrane unit including membranes, seals, potting material, associated valving and piping, and all other components which under compromised conditions could result in contamination of the filtrate.

Common direct integrity tests include those that apply pressure or vacuum (such as the pressure decay test and diffusive airflow test) and those that measure the rejection of a particulate or molecular marker (such as spiked particle monitoring). Today's final rule does not stipulate the use of a particular direct integrity test. Instead, the direct integrity test must meet performance criteria for resolution, sensitivity, and frequency.

''Resolution'' is defined as the smallest leak that contributes to the response from a direct integrity test. Any direct integrity test applied to meet the requirements of this rule must have a resolution of 3 micrometers or less. The manner in which resolution is determined will depend on the type of direct integrity test used (*i.e.*, pressure-based versus marker-based tests).

''Sensitivity'' is defined as the maximum LRV that can be reliably verified by the direct integrity test. The sensitivity of the direct integrity test applied to a membrane filtration process to meet the Cryptosporidium treatment requirements of this rule must be equal to or greater than the removal credit awarded to the membrane filtration process. Furthermore, the increased concentration of suspended solids that occurs on the high pressure side of the membrane in some module designs must be considered in the sensitivity determination (*i.e.*, the scouring action of some membrane designs keeps the accumulated solids in suspension where they may pass through an integrity breach). Specifically, the sensitivity of the direct integrity test is reduced by a factor that quantifies the increased concentration of suspended solids relative to the feed concentration.

The ''frequency'' of direct integrity testing specifies how often the test is performed over an established time interval. Direct integrity tests available at the time of promulgation are applied periodically and must be conducted on each membrane unit at a frequency of not less than once per day that the unit is in operation, unless the State determines that less frequent testing is acceptable. If continuous direct integrity test methods become available that also meet the sensitivity and resolution criteria described earlier, such a continuous test may be used in lieu of periodic testing.

PWSs must establish a direct integrity test control limit that is indicative of an integral membrane unit capable of meeting the Cryptosporidium removal credit awarded to the membrane. If the control limit for the direct integrity test is exceeded, the membrane unit must be taken off-line for diagnostic testing and repair. The membrane unit may only be returned to service after the repair has been completed and confirmed through the application of a direct integrity test. A monthly report must be submitted to the State summarizing all direct integrity test results above the control limit and the corrective action that was taken in each case.

Continuous Indirect Integrity Monitoring

Available direct integrity test methods are applied periodically since the membrane unit must be taken out of service to conduct the test. In order to provide some measure of process performance between direct integrity testing events, PWSs must perform continuous indirect integrity monitoring on each membrane unit. Continuous indirect integrity monitoring is defined as monitoring some aspect of filtrate water quality that is indicative of the removal of particulate matter at a frequency of at least once every 15 minutes. If a continuous direct integrity test is implemented that meets the resolution and sensitivity criteria described previously in this section, continuous indirect integrity monitoring is not required.

Unless the State approves an alternative parameter, continuous indirect integrity monitoring must include continuous filtrate turbidity monitoring. If the filtrate turbidity readings are above 0.15 NTU for a period greater than 15 minutes, the PWS must perform direct integrity testing on the associated membrane unit.

If the State approves an alternate parameter for continuous indirect integrity monitoring, the State must approve a control limit for that parameter. If the parameter exceeds the control limit for a period greater than 15 minutes, the PWS must perform direct integrity testing on the associated membrane unit.

PWSs must submit a monthly report to the State summarizing all continuous indirect integrity monitoring results triggering direct integrity testing and the corrective action that was taken in each case.

EPA has developed the Membrane Filtration Guidance Manual to assist

systems with implementation of these requirements. This guidance may be requested from EPA's Safe Drinking Water Hotline, which may be contacted as described under **FOR FURTHER INFORMATION CONTACT** in the beginning of this notice.

b. Background and Analysis

In the August 11, 2003 proposed LT2ESWTR, EPA proposed to establish criteria for awarding credit to membrane filtration processes for removal of Cryptosporidium (USEPA 2003g). The Agency based these criteria on data demonstrating the Cryptosporidium removal efficiency of membrane filtration processes, a critical evaluation of available integrity monitoring techniques, and study of State approaches to the regulation of membrane filtration for pathogen removal. This information is summarized in the report Low-Pressure Membrane Filtration for Pathogen Removal: Application, Implementation, and Regulatory Issues (USEPA 2001g).

As summarized in this report, a number of studies demonstrate the ability of membrane filtration processes to remove pathogens, including Cryptosporidium, to below detection levels (USEPA 2001g). In some studies that used Cryptosporidium seeding, measured removal efficiencies were as high as 7-log (Jacangelo, et al., 1997; Hagen, 1998; Kachalsky and Masterson, 1993). In other studies, removal efficiencies ranged from 4.4- to 6.5-log and were only limited by the seeded concentration of Cryptosporidium oocysts (Dwyer, et al. 1995, Jacangelo et al. 1989, Trussel, et al. 1998, NSF 2000a–g, Olivieri 1989). Collectively, these results demonstrate that an integral membrane module (i.e., a membrane module without any leaks or defects, with an exclusion characteristic smaller than Cryptosporidium) is capable of removing this pathogen to below detection in the filtrate, independent of the influent concentration.

The 2003 proposal included a provision for challenge testing membranes to demonstrate the removal efficiency of Cryptosporidium. EPA believes this requirement is necessary due to the proprietary nature of these products and the lack of any uniform design criteria for establishing the exclusion characteristic of a membrane. Guidance on the design and conduct of a challenge test to meet the requirements of this rule is presented in the Membrane Filtration Guidance Manual.

Challenge testing is required on a product-specific basis, rather than a site-specific basis; thus, modules used in full-scale facilities will generally not be directly challenge tested. The removal capability of production membrane modules is verified through the application of a non-destructive performance test, such as a bubble point test. A quality control release value (QCRV) for the non-destructive performance test can be related to the results of the challenge test and used to demonstrate the ability of production modules to achieve the Cryptosporidium removal efficiency demonstrated during challenge testing. Most membrane manufacturers have adapted some form of non-destructive testing for the purpose of product quality control and have established a QCRV that is indicative of an acceptable product. It may be possible to apply these existing practices to meet the requirements of today's final rule.

While challenge testing demonstrates the removal efficiency of an integral membrane module, defects or leaks in the membrane or other system components can result in contamination of the filtrate unless they are identified, isolated, and repaired. In order to verify continued performance of a membrane system, today's final rule requires direct integrity testing of membrane filtration processes used to meet the Cryptosporidium treatment requirements of this rule.

An evaluation of available direct integrity tests indicates that pressure-based tests are widely applied and sufficiently sensitive to provide verification of removal efficiencies in excess of 4-log. Marker-based direct integrity tests are also available, and new direct integrity tests may be developed that present an improvement over existing tests. Rather than specify a particular direct integrity test, today's final rule defines performance criteria for direct integrity testing. These criteria are resolution, sensitivity, and frequency, as previously described. EPA believes that this approach will provide flexibility for the development and implementation of future innovations in direct integrity testing while ensuring that any test applied to meet the requirements of this rule will achieve the required level of performance.

Since available direct integrity tests require taking the membrane unit out of service to conduct the test, today's rule establishes a minimum test frequency for direct integrity testing. Currently, there is no standard frequency for direct integrity testing that has been adopted by all States and membrane treatment facilities. In a 2000 survey, the required frequency of integrity testing was found to vary from once every four hours to once per week; however, the most common frequency for conducting a direct integrity test was once every 24 hours (USEPA 2001g). Specifically, 10 out of 14 States that require periodic direct integrity testing specify a frequency of once per day. Furthermore, many membrane manufacturers of systems with automated integrity test systems set up the membrane units to automatically perform a direct integrity test once per day.

EPA believes that daily direct integrity testing is appropriate for most membrane filtration installations, but under some circumstances, less frequent testing may be adequate. Thus, EPA is allowing States to approve less frequent direct integrity testing on the basis of demonstrated process reliability, use of multiple barriers effective for Cryptosporidium, or reliable process safeguards.

Due to the periodic nature of direct integrity testing, today's rule includes a provision for continuous indirect integrity monitoring. While indirect monitoring is not as sensitive as direct testing, it provides an indication of process performance to ensure that a major failure has not occurred between application of direct integrity tests.

c. Summary of Major Comments

In response to the 2003 proposal, the Agency received significant comments on the following issues related to membrane filtration: the frequency of direct integrity testing; the procedure necessary to determine removal credit for membrane filtration; and the requirement for continuous indirect integrity monitoring.

The 2003 proposal requested comment on the proposed minimum direct integrity test frequency of once per day. Some commenters supported the daily frequency and commented that many states have already adopted this standard. Others commented that direct integrity testing once per day is too frequent, citing the lack of data in the proposal documenting the rate of membrane failure, as well as the loss in production that occurs when the membrane unit is taken off-line for testing.

While EPA recognizes these concerns, a critical factor in establishing a testing frequency is the amount of time that water from a compromised membrane unit is supplied to the public before the integrity breach is detected. EPA believes that this factor is most important to public health protection and that daily direct integrity testing is appropriate for the majority of membrane systems. However, EPA also acknowledges that there may be

circumstances under which less frequent testing may provide adequate public health protection, and has revised the rule to allow States to permit less frequent direct integrity testing based on demonstrated process reliability, use of multiple barriers effective for Cryptosporidium, or reliable process safeguards.

Several commenters expressed concern with the process needed to determine appropriate removal credit for membrane filtration. However, many commenters also supported the flexibility provided to States in determining the appropriate removal credit for membrane filtration based on the criteria defined in the 2003 proposal. EPA believes that the proposed approach for awarding Cryptosporidium removal credit to membrane filtration is supported by the available data and analysis, and will allow higher removal credits to be considered on a scientifically sound basis. EPA recognizes that the flexibility provided in the regulation does increase the complexity of determining removal credits for membrane filtration. To address this issue, EPA has developed extensive guidance to support the implementation of requirements for membrane filtration.

EPA received comment that continuous indirect integrity monitoring is unnecessary due to the poor sensitivity of currently available methods. EPA acknowledges that currently available indirect monitoring methods are less sensitive than available direct integrity tests. However, EPA believes that continuous indirect integrity monitoring is necessary to protect public health. Specifically, continuous monitoring may alert a system of potentially severe integrity breaches that could result in bypass of unfiltered water around the membrane filtration process and pose a risk to public health. Furthermore, EPA has provided States with the flexibility to permit use of more sensitive continuous indirect monitoring methods and/or to establish lower control limits. Also, implementation of continuous direct integrity testing would preclude the need to implement any form of indirect integrity monitoring.

12. Second Stage Filtration

a. Today's Rule

PWSs may receive 0.5-log credit towards the Cryptosporidium treatment requirements of today's rule for a second filtration stage. To be eligible for this credit, the second-stage filtration must meet the following criteria:

- The filter must be a separate second stage of granular media filtration, such as sand, dual media, or granular activated carbon (GAC), that follows a first stage of granular media filtration (e.g., follows a conventional treatment or direct filtration plant).
- The first filtration stage must be preceded by a coagulation process.
- Both filtration stages must treat 100 percent of the treatment plant flow.
- The State must approve the treatment credit based on an assessment of the design characteristics of the filtration process.

This microbial toolbox option does not apply to bag filters, cartridge filters, membranes, or slow sand filters, which are addressed separately in the microbial toolbox. Further, this options does not apply to roughing filters, which are pretreatment processes that typically consist of coarse media and are not preceded by coagulation. States may consider awarding treatment credit to roughing filters under a demonstration of performance.

PWSs may not receive additional treatment credit for both second-stage filtration and lower filter effluent turbidity (*i.e.*, combined or individual filter performance) that is based on turbidity levels following the second filtration stage. PWSs may receive credit for both options based on turbidity following the first filtration stage.

b. Background and Analysis

The Stage 2 M–DBP Advisory Committee recommended a 0.5-log Cryptosporidium treatment credit for a roughing filter with the stipulation that EPA identify the design and operational conditions under which such credit is appropriate. After reviewing available data, however, EPA was unable to determine conditions under which a roughing filter is likely to achieve at least 0.5-log removal of Cryptosporidium. Roughing filters consist of coarse media like gravel and usually are not preceded by coagulation. They are used to remove sediment and large particulate matter from raw water prior to the primary treatment processes. EPA identified no studies indicating that roughing filters would be effective for removal of Cryptosporidium (USEPA 2003a).

In contrast, numerous studies have demonstrated that granular media filtration can be effective for removing Cryptosporidium when preceded by coagulation (Patania et al. 1995, Nieminski and Ongerth 1995, Ongerth and Pecoraro 1995, LeChevallier and Norton 1992, LeChevallier et al. 1991, Dugan et al. 2001, Nieminski and Bellamy 2000, McTigue et al. 1998, Patania et al. 1999, Huck et al. 2000, Emelko et al. 2000). PWSs may implement a second granular media filtration stage to achieve various water quality objectives, such as increased removal of organic material in biologically active filters or removal of inorganic contaminants. Consequently, EPA believes that consideration of additional Cryptosporidium treatment credit for a second granular media filtration stage is appropriate.

The August 11, 2003 LT2ESWTR proposal included an additional 0.5-log Cryptosporidium treatment credit for PWSs that use a second separate filtration stage consisting of rapid sand, dual media, GAC, or other fine grain media. A cap, such as GAC, on a single stage of filtration did not qualify. In addition, the proposal required the first stage of filtration to be preceded by a coagulation step and both stages had to treat 100 percent of the plant flow. Today's final rule establishes this treatment credit with minimal changes from the proposal. The basis for this credit and for changes from the proposed rule are summarized in the following discussion.

While the studies of Cryptosporidium removal by granular media filtration cited previously evaluated only a single stage of filtration, the same removal mechanisms will be operative in a second stage of granular media filtration. Secondary filters may remove Cryptosporidium that were destabilized but not trapped in primary filters or that were trapped but subsequently detached from primary filters prior to backwash. Thus, EPA believes these studies are supportive of additional removal credit for a second filtration stage.

An important finding of these studies is that coagulation is necessary to achieve significant Cryptosporidium removal by granular media filtration (does not apply to slow sand filtration, which is addressed in the next section). Consequently, today's rule requires that the first filtration stage be preceded by coagulation for a PWS to receive treatment credit for second-stage filtration. This requirement is necessary to ensure that both filtration stages are effective for Cryptosporidium removal. PWSs will already comply with this requirement where a second filtration stage is applied after conventional treatment or direct filtration.

In the proposal, EPA also reviewed data provided by a PWS on the removal of aerobic spores through GAC filters (i.e., contactors) following conventional treatment. As discussed earlier, studies have demonstrated that aerobic spores can serve as an indicator of Cryptosporidium removal by granular

media filtration (Dugan et al. 2001, Emelko et al. 1999 and 2000, Yates et al. 1998, Mazounie et al. 2000). Over a two year period, the mean removal of aerobic spores across the GAC filters exceeded 0.5-log. These results support the finding that a second stage of granular media filtration can reduce Cryptosporidium levels by 0.5-log or greater.

Today's rule does not establish design criteria such as filter depth or media size for second-stage filters to be eligible for treatment credit. While filter design will influence Cryptosporidium removal efficiency, EPA recognizes that appropriate filter designs will vary depending on the application. States have traditionally provided oversight for treatment process designs in PWSs. Accordingly, today's rule requires State review and approval of second-stage filter design as a condition for PWSs to receive additional treatment credit for this process. The Microbial Toolbox Guidance Manual addresses second-stage filtration for Cryptosporidium treatment credit.

c. Summary of Major Comments

Public comment on the August 11, 2003 LT2ESWTR proposal generally supported additional treatment credit for second-stage filtration. Commenters raised specific concerns with EPA establishing design requirements for filtration, the sufficiency of data to support prescribed treatment credit, and the expansion of this credit to include other filtration technologies. These comments and EPA's responses are summarized as follows.

In the proposal, EPA requested comment on whether a minimum filter depth should be required for PWSs to receive treatment credit for a second filtration stage. All commenters opposed EPA setting regulatory design standards for filters on the basis that PWSs and States need the flexibility to determine appropriate treatment designs. In response, EPA agrees that effective filter designs will vary depending on the application. Consequently, EPA is not establishing filter design criteria in today's rule, but is requiring that States approve designs for PWSs to receive treatment credit for second-stage filtration.

Many commenters stated that available data support the prescribed 0.5-log Cryptosporidium treatment credit for second-stage filtration. Some commenters provided additional data on the removal of aerobic spores through GAC filters following conventional treatment that showed a mean reduction greater than 1-log. In contrast, other commenters were concerned about the lack of data to support increased removal through a second filtration stage. These commenters recommended that treatment credit for second-stage filtration should be awarded only on a site-specific basis through a demonstration of performance.

EPA has concluded that available data are sufficient to support the prescribed 0.5-log treatment credit for second-stage filtration. Studies of granular media filtration demonstrate high levels of Cryptosporidium removal and one study has shown greater than 1.0-log removal through secondary GAC filters. Secondary filters can remove Cryptosporidium that pass through or detach from the primary filters. This added removal will help to stabilize finished water quality by providing a barrier during periods of the filtration cycle when the primary filters are not performing optimally. Therefore, EPA is establishing this credit in today's rule.

Several commenters recommended that EPA expand the second-stage filtration option to include membranes, bag filters, and DE filtration. EPA notes that today's rule establishes prescribed treatment credits specifically for bag and cartridge filters and membranes as microbial toolbox options, and prescribed credit for DE filtration is addressed in section IV.B. PWSs may seek treatment credit for other filtration technologies through a demonstration of performance under today's rule.

13. Slow Sand Filtration

a. Today's Rule

PWSs may receive a 2.5-log credit towards the Cryptosporidium treatment requirements in today's rule for implementing slow sand filtration as a secondary filtration stage following a primary filtration process. To be eligible for this credit, the slow sand filtration must meet the following criteria:

- The slow sand filter must be a separate second stage of filtration that follows a first stage of filtration like conventional treatment or direct filtration;
- There must be no disinfectant residual in the influent water to the slow sand filtration process;
- Both filtration stages must treat 100 percent of the treatment plant flow from a surface water or GWUDI source; and
- The State must approve the treatment credit based on an assessment of the design characteristics of the filtration process.

Slow sand filtration used as a primary filtration process receives a prescribed 3-log Cryptosporidium treatment credit, as described in section IV.B.

b. Background and Analysis

Slow sand filtration is a process involving passage of raw water through a bed of sand at low velocity (generally less than 0.4 m/h), resulting in substantial particulate removal. Several studies have demonstrated that slow sand filtration can achieve significant Cryptosporidium removal (Schuler and Ghosh, 1991, Timms et al. 1995, Hall et al. 1994). Slow sand filtration is typically used as a primary filtration process, usually in small systems, rather than as a secondary filtration stage following conventional treatment or another primary filtration process. EPA expects, however, that slow sand filtration would be effective for Cryptosporidium removal in such an application, which warrants consideration of treatment credit under today's rule.

The Stage 2 M–DBP Advisory Committee recommended that slow sand filtration receive 2.5-log or greater Cryptosporidium treatment credit when used in addition to existing treatment that achieves compliance with the IESWTR or LT1ESWTR. The August 11, 2003 LT2ESWTR proposal included 2.5-log treatment credit for slow sand as a secondary filtration process, with the only associated condition being no disinfectant residual in the water influent to the filter. In today's rule, EPA is establishing this treatment credit with minimal changes from the proposal. The following discussion summarizes the basis for this credit and for changes from the proposal.

Removal of microbial pathogens in slow sand filters is complex and is believed to occur through a combination of physical, chemical, and biological mechanisms, both on the surface and in the interior of the filter bed. In particular, biological activity in the upper layers of the filter is believed to promote microbial removal. Based on previously cited studies demonstrating greater than 4-log removal of Cryptosporidium through slow sand filtration, today's rule awards a prescribed 3-log Cryptosporidium removal credit to slow sand filtration as a primary filtration process.

The effectiveness of slow sand as a secondary filtration process is more uncertain. In general, EPA expects that the same microbial removal mechanisms will be operative. However, due to the quality of treated water following a primary filtration process, filter ripening and development of the biologically active layer in a secondary slow sand filter may be inhibited. One study that evaluated Cryptosporidium removal by slow sand filtration alone

and slow sand filtration preceded by a rapid sand filter observed similar removal levels in the two treatment trains (Hall et al. 1994). Because of the uncertainty regarding the performance of slow sand as a secondary filtration step and in consideration of the Advisory Committee recommendation, today's rule establishes a 2.5-log additional Cryptosporidium treatment credit for this application.

Due to the importance of biological activity to slow sand filter performance, PWSs may not receive the prescribed treatment credit if the influent water to the slow sand filter contains a disinfectant residual. EPA is not establishing design standards for slow sand filters in today's rule. Studies have shown, however, that design deficiencies in slow sand filters may lead to poor Cryptosporidium removal (Fogel et al. 1993). Consequently, States must approve slow sand filter designs as a secondary filtration stage for PWSs to receive treatment credit under today's rule.

c. Summary of Major Comments

Public comment on the August 11, 2003 proposal focused on the question of whether the 2.5-log Cryptosporidium treatment credit for slow sand as a secondary filtration process is appropriate. Many commenters supported the proposed treatment credit. These commenters cited studies demonstrating greater than 4-log Cryptosporidium removal by slow sand filtration and concluded that the data justify a 2.5-log treatment credit for slow sand filtration added to a clarification and filtration treatment train.

Several commenters, however, stated that this treatment credit is not justified due to the lack of data on the performance of slow sand as a secondary filtration step. Available studies on slow sand filter performance for Cryptosporidium removal have mostly been conducted on raw (i.e., unfiltered) water. These commenters were concerned that if slow sand filtration is applied following a primary filtration process, the filter ripening period and other factors will be significantly affected. As a result, the slow sand filtration may provide only limited removal over a long ripening period.

In response, EPA recognizes that little testing has been conducted on the performance of slow sand filtration specifically as a second filtration stage in a treatment train. However, available data do not indicate that slow sand filtration would be substantially less effective when used in this capacity. Slow sand filtration is recommended only for higher quality source waters, and water quality following a primary filtration process would be well within recommended design limits for slow sand filtration (USEPA 1991a). EPA agrees that filter ripening is critical to slow sand filtration achieving its full performance level, and this process may require more time when slow sand filtration follows a primary filtration process. However, this effect may be counterbalanced by very long filter run times between cleaning the filter due to the high quality influent water. Consequently, EPA believes that 2.5-log Cryptosporidium treatment credit for slow sand as a secondary filtration process is warranted.

14. Ozone and Chlorine Dioxide

a. Today's Rule

PWSs may use ozone and chlorine dioxide to meet Cryptosporidium treatment requirements under today's rule. To receive treatment credit, PWSs must measure the water temperature, disinfectant contact time, and residual disinfectant concentration at least once each day and determine the log inactivation credit using the tables in this section. Specific criteria are as follows:

- The temperature of the disinfected water must be measured at least once per day at each residual disinfectant concentration sampling point.
- The disinfectant contact time(s) (''t'') must be determined for each day during peak hourly flow.
- The residual disinfectant concentration(s) (''C'') of the water before or at the first customer must be measured each day during peak hourly flow.
- Tables IV.D–3 or IV.D–4 must be used to determine Cryptosporidium log inactivation credit for ozone or chlorine dioxide, respectively, based on the water temperature and the product of disinfectant concentration and contact time (CT).

TABLE IV.D–3.—CT VALUES FOR CRYPTOSPORIDIUM INACTIVATION BY OZONE [1] (MG/L × MIN)

Log credit	Water temperature, °C										
	≤0.5	1	2	3	5	7	10	15	20	25	30
0.25	6.0	5.8	5.2	4.8	4.0	3.3	2.5	1.6	1.0	0.6	0.39
0.5	12	12	10	9.5	7.9	6.5	4.9	3.1	2.0	1.2	0.78
1.0	24	23	21	19	16	13	9.9	6.2	3.9	2.5	1.6
1.5	36	35	31	29	24	20	15	9.3	5.9	3.7	2.4
2.0	48	46	42	38	32	26	20	12	7.8	4.9	3.1
2.5	60	58	52	48	40	33	25	16	9.8	6.2	3.9
3.0	72	69	63	57	47	39	30	19	12	7.4	4.7

[1] PWSs may use this equation to determine log credit between the indicated values: Log credit = $(0.0397 \times (1.09757)^{Temp}) \times CT$.

TABLE IV.D–4.—CT VALUES FOR CRYPTOSPORIDIUM INACTIVATION BY CHLORINE DIOXIDE [1] (MG/L × MIN)

Log credit	Water temperature, °C										
	≤0.5	1	2	3	5	7	10	15	20	25	30
0.25	159	153	140	128	107	90	69	45	29	19	12
0.5	319	305	279	256	214	180	138	89	58	38	24
1.0	637	610	558	511	429	360	277	179	116	75	49
1.5	956	915	838	767	643	539	415	268	174	113	73
2.0	1275	1220	1117	1023	858	719	553	357	232	150	98
2.5	1594	1525	1396	1278	1072	899	691	447	289	188	122
3.0	1912	1830	1675	1534	1286	1079	830	536	347	226	147

[1] PWSs may use this equation to determine log credit between the indicated values: Log credit = $(0.001506 \times (1.09116)^{Temp}) \times CT$.

PWSs may have several disinfection segments in sequence along the treatment train, where a disinfectant segment is defined as a treatment unit process with a measurable disinfectant residual level and a liquid volume. In determining the total log inactivation, the PWS may calculate the CT for each disinfection segment and use the sum of these values to determine the log inactivation achieved through the plant. The Toolbox Guidance Manual provides information on recommended methodologies for determining CT values for different disinfection reactor designs and operations.

Alternatively, the State may approve alternative CT values to those specified in Tables IV.D–3 or IV.D–4 based on a site-specific study a PWSs conducts following a State-approved protocol. The Toolbox Guidance Manual describes recommended approaches for making such demonstrations.

b. Background and Analysis

Ozone and chlorine dioxide are chemical disinfectants that have been shown to be effective for inactivating Cryptosporidium. The Stage 2 M–DBP Advisory Committee recommended that EPA develop criteria for PWSs to achieve Cryptosporidium inactivation credit with these disinfectants. The August 11, 2003 LT2ESWTR proposal included CT values for 0.5- to 3-log Cryptosporidium inactivation credit by ozone or chlorine dioxide at temperatures ranging from less than 0.5 C to 25 C, along with daily required monitoring (USEPA 2003a). Today's final rule establishes these criteria with no changes from the proposed rule, but expands the CT tables down to 0.25-log inactivation and up to a water temperature of 30 C. The following discussion summarizes the basis for these criteria.

The requirements for at least daily monitoring of the water temperature, residual disinfectant concentration, and contact time during peak hourly flow to determine a daily inactivation level reflect existing requirements for Giardia inactivation by chemical disinfection in 40 CFR 141.74. EPA expects that in practice, many PWSs using ozone or chlorine dioxide will monitor more frequently and for multiple disinfectant segments. In the Toolbox Guidance Manual, EPA provides information on recommended approaches for monitoring and calculating CT values for ozone and chlorine dioxide reactors.

The CT values for both ozone and chlorine dioxide are based on analyses by Clark *et al.* (2002a,b), with additional procedures to assess confidence bounds. Clark *et al.* (2002a,b) developed predictive equations for Cryptosporidium inactivation through evaluating studies on ozone by Rennecker *et al.* (1999), Li *et al.* (2001), Owens *et al.* (2000), and Oppenheimer *et al.* (2000) and on chlorine dioxide by Li *et al.* (2001), Owens *et al.* (1999) and Ruffell *et al.* (2000). EPA applied confidence bounds to these predictive equations to ensure that PWSs operating at a given CT value are likely to achieve at least the corresponding log inactivation level in the CT table.

In identifying confidence bounds for CT values, EPA was primarily concerned with uncertainty in the estimations by Clark *et al.* (2002a,b) of the linear relationship between log inactivation and CT (*i.e.*, uncertainty in the regression) and with real variability in the inactivation rate. Such real variability could be associated with different populations of oocysts and different water matrices. In contrast, variability associated with experimental error, such as the assays used to measure loss of infectivity, was a lessor concern. The purpose of the CT tables is to ensure a given level of inactivation and not to predict the measured result of an individual experiment.

For developing earlier CT values, EPA has used bounds for confidence in prediction, which account for both real variability and experimental error. EPA believes that this approach was appropriate due to limited inactivation data and uncertainty in the sources of variability in the data. However, the high doses of ozone and chlorine dioxide necessary to inactivate Cryptosporidium create an offsetting concern with the formation of DBPs (*e.g.*, bromate and chlorite). In consideration of this concern, EPA has employed a less conservative method to calculate confidence bounds for the ozone and chlorine dioxide CT values in today's rule; specifically, EPA has attempted to exclude experimental error from the confidence bounds.

In order to estimate confidence bounds that exclude experimental error, EPA assessed the relative contribution of experimental error to the variance observed in the Cryptosporidium inactivation data sets. This assessment was done by comparing variance among data points with consistent experimental conditions, which was attributed to experimental error, with the total variance in a data set. By this analysis, EPA estimated that 87.5 and 62 percent of the variance in the Cryptosporidium inactivation data for ozone and chlorine dioxide, respectively, could be ascribed to experimental error (Sivaganesan 2003, Messner 2003). EPA then applied these estimates to the predictive equations developed by Clark *et al.* (2002a,b) using a modified form of a formula for calculating a 90 percent confidence bound (Messner 2003).

This analysis produced the CT values shown in tables IV.D–3 and IV.D–4 for ozone and chlorine dioxide, respectively. CT values are provided for inactivation as low as 0.25-log. Such a low inactivation level may be used by PWSs applying ozone in combination with other disinfectants. Available data do not support the determination of conditions for inactivation greater than 3-log, so the CT values in today's rule do not go beyond this level. The temperature range of CT values in today's rule goes to 30 C (86 F), which will accommodate most natural waters. If the water temperature is higher than 30 C, temperature should be set to 30 C for the log inactivation calculation. PWSs may use the equations provided as footnotes to tables IV.D–3 and IV.D–4 to interpolate between CT values.

EPA recognizes that inactivation rates may be sensitive to water quality and operational conditions at individual PWSs. To reflect this potential, PWSs are allowed to perform a site-specific inactivation study to determine CT requirements. The State must approve the protocols or other information used to derive alternative CT values. EPA has provided guidance for such studies in the Toolbox Guidance Manual.

c. Summary of Major Comments

Public comment on the August 11, 2003 LT2ESWTR proposal supported the inclusion of ozone and chlorine dioxide in the microbial toolbox for Cryptosporidium inactivation. Commenters stated concerns with the required criteria for achieving Cryptosporidium treatment credit, including the conservatism EPA applied in developing the CT tables, the ability of PWSs with different types of source waters to use these disinfectants, and the range of conditions covered by the CT tables. Commenters also made recommendations for guidance. These comments and EPA's responses are summarized as follows.

Some commenters supported the proposed CT tables, but others stated that the statistical approach used to calculate the confidence bounds from which the CT values are derived is overly conservative. These commenters were concerned that this approach will increase capital and operating costs and lead to higher byproduct levels.

In response, EPA believes that the confidence bounds used for the ozone and chlorine dioxide CT tables in today's rule are appropriate and

necessary to ensure that PWSs achieve intended levels of Cryptosporidium inactivation. They account only for uncertainty in the regression of inactivation data and for variability in inactivation data that cannot be attributed to experimental error. This approach is significantly less conservative than the approaches used in CT tables for earlier rules. EPA employed this less conservative approach in recognition of the high disinfectant doses necessary for Cryptosporidium inactivation and concern with byproducts.

Commenters were concerned that due to the relatively high ozone and chlorine dioxide doses necessary for Cryptosporidium inactivation, some PWSs will be unable to use these disinfectants to achieve required levels of Cryptosporidium treatment. In particular, using ozone for high Cryptosporidium inactivation levels will be difficult in areas where cold water temperatures would necessitate especially high doses or where high source water bromide levels would cause problems with bromate formation. The use of chlorine dioxide for Cryptosporidium inactivation may be difficult due to chlorite formation.

EPA recognizes that the use of ozone and chlorine dioxide to achieve Cryptosporidium inactivation will depend on source water factors and will not be feasible for all PWSs. Due to the availability of UV, which EPA has determined to be a feasible technology for Cryptosporidium inactivation by all PWS sizes, the feasibility of today's rule does not depend on the widespread use of ozone or chlorine dioxide for compliance. In assessing the impact of today's rule on PWSs, EPA used ICR survey data to estimate the fraction of PWSs that could use ozone or chlorine dioxide to achieve different levels of Cryptosporidium inactivation without exceeding DBP MCLs (see Economic Analysis for the LT2ESWTR). While EPA expects that some PWSs will use these disinfectants, the microbial toolbox provides many other options for PWSs to comply with the Cryptosporidium treatment requirements of today's rule.

Commenters recommended that EPA expand the range of conditions encompassed in the CT tables. Specifically, commenters asked that CT tables include values for water temperatures above 25 C and supported this request by providing data showing temperature profiles for water sources with maximum temperatures near 30 C. Commenters also requested CT values for Cryptosporidium inactivation levels below 0.5-log for PWSs that will use multiple disinfectants to meet the treatment requirements in today's rule. In addition, commenters suggested that EPA provide equations that PWSs can use to interpolate between the listed CT values.

EPA has addressed these recommendations in today's final rule. The CT tables for ozone and chlorine dioxide include values for a water temperature of 30 C and for 0.25-log inactivation. Footnotes to these tables contain equations that PWSs can use to calculate log inactivation credit for conditions between those provided in the tables. PWSs may use these equations in their process control systems.

Commenters made recommendations for guidance on the use of ozone and chlorine dioxide to comply with today's rule. These recommendations concern topics like monitoring disinfection reactors, procedures for calculating disinfectant concentration and contact time, site specific studies, and synergistic effects of multiple disinfectants. EPA has addressed these topics in the Toolbox Guidance Manual.

15. Ultraviolet Light

a. Today's Rule

PWSs may use ultraviolet (UV) light to comply with Cryptosporidium treatment requirements in today's rule, as well as Giardia lamblia and virus treatment requirements in existing regulations. To receive treatment credit, PWSs must operate UV reactors validated to achieve the required UV dose, as shown in the table in this section, and monitor their UV reactors to demonstrate operation within validated conditions. Specific criteria are as follows:

Required UV Doses

• UV dose (fluence) is the product of the UV intensity over a surface area (fluence rate) and the exposure time. PWSs must use validation testing to demonstrate that a UV reactor achieves the UV doses shown in Table IV.D–5 in order to receive the associated inactivation credit.

TABLE IV.D–5.—UV DOSE REQUIREMENTS FOR CRYPTOSPORIDIUM, GIARDIA LAMBLIA, AND VIRUS INACTIVATION CREDIT

Log credit	Cryptosporidium UV dose (mJ/cm^2)	Giardia lamblia UV dose (mJ/cm^2)	Virus UV dose (mJ/cm^2)
0.5	1.6	1.5	39
1.0	2.5	2.1	58
1.5	3.9	3.0	79
2.0	5.8	5.2	100
2.5	8.5	7.7	121
3.0	12	11	143
3.5	15	15	163
4.0	22	22	186

• The dose values in Table IV.D–5 are for UV light at a wavelength of 254 nm as delivered by a low pressure mercury vapor lamp. However, PWSs may use this table to determine treatment credits for other lamp types through validation testing, as described in the UV Disinfection Guidance Manual. The dose values in Table IV.D–5 apply to post-filter applications of UV in filtration plants and to PWSs that meet all applicable filtration avoidance criteria.

UV Reactor Validation Testing

• The validation test may be reactor-specific or site-specific. Unless the State approves an alternative approach, this testing must involve the following: (1) Full scale testing of a reactor that conforms uniformly to the UV reactors used by the PWS, and (2) inactivation of a test microorganism whose dose response characteristics have been quantified with a low pressure mercury vapor lamp.

• Validation testing must identify ranges for parameters the PWS can monitor to ensure that the required UV dose is delivered during operation. These parameters must include flow rate, UV intensity as measured by UV sensors, and UV lamp status.

• The operating parameters determined by validation testing must

account for the following factors: (1) UV absorbance of the water, (2) lamp fouling and aging, (3) measurement uncertainty of UV sensors, (4) dose distributions arising from the flow velocity profiles through the reactor, (5) failure of UV lamps or other critical system components, and (6) inlet and outlet piping or channel configurations of the UV reactor. In the UV Disinfection Guidance Manual, EPA describes recommended approaches for reactor validation that address these factors.

UV Reactor Monitoring

- PWSs must monitor for the parameters necessary to demonstrate operation within the validated conditions of the required UV dose. These parameters must include flow rate, UV intensity as measured by UV sensors, and UV lamp status. PWSs must check the calibration of UV sensors and recalibrate in accordance with a protocol approved by the State.
- For PWSs using UV light to meet microbial treatment requirements, at least 95 percent of the water delivered to the public every month must be treated by UV reactors operating within validated conditions for the required UV dose.

b. Background and Analysis

Numerous studies have demonstrated that UV light is effective for inactivating Cryptosporidium, Giardia lamblia, and other microbial pathogens at relatively low doses (Clancy et al. 1998, 2000, 2002, Bukhari et al. 1999, Craik et al. 2000, 2001, Landis et al. 2000, Sommer et al. 2001, Shin et al. 2001, and Oppenheimer et al. 2002). EPA has determined that UV light is a feasible technology for PWSs of all sizes to inactivate Cryptosporidium. Accordingly, EPA expects that UV is one of the primary technologies PWSs will use to comply with Cryptosporidium treatment requirements in today's rule.

The Stage 2 M–DBP Advisory Committee recommended that EPA establish standards for the use of UV to comply with drinking water treatment requirements. These standards include the UV doses necessary for different levels of Cryptosporidium, Giardia lamblia, and virus inactivation and a protocol for validating the disinfection performance of UV reactors. The Committee also directed EPA to develop a UV disinfection guidance manual to familiarize States and PWSs with important design and operational issues for UV installations.

The August 11, 2003 LT2ESWTR proposal included UV doses for PWSs to achieve treatment credit of up to 3-log for Cryptosporidium and Giardia lamblia and up to 4-log for viruses, along with associated reactor validation and monitoring requirements. The proposal also required unfiltered PWSs using UV to achieve the UV dose for the required level of Cryptosporidium inactivation in at least 95 percent of the water delivered to the public every month (USEPA 2003a).

Today's final rule establishes these criteria with no changes from the proposed rule. However, EPA has expanded the UV dose table to include 4-log inactivation of Cryptosporidium and Giardia lamblia and has expanded the 95 percent compliance requirement to include filtered PWSs and to cover Giardia lamblia and virus inactivation. The following discussion summarizes the basis for these criteria.

The UV dose values in Table IV.D–5 are based on meta-analyses of UV inactivation studies with Cryptosporidium parvum, Giardia lamblia, Giardia muris, and adenovirus (Qian et al. 2004, USEPA 2003a). EPA has expanded the dose values for Cryptosporidium and Giardia lamblia from 3- to 4-log inactivation because available data support criteria for this level of treatment. Neither today's rule nor any existing regulations require PWSs to provide Cryptosporidium inactivation above this level, so EPA has not expanded the UV dose tables further. While today's rule requires up to 5.5-log Cryptosporidium treatment by filtered PWSs, at least 2.0-log of this treatment must be achieved by physical removal.

The required UV doses for inactivation of viruses are based on the dose-response of adenovirus because among waterborne pathogenic viruses that have been studied, it appears to be the most UV resistant. As summarized in Embrey (1999), adenoviruses have been identified as the second most important agent of gastroenteritis in children and can cause significant adverse health effects, including death, in persons with compromised immune systems. They are associated with fecal contamination in water and have been implicated in waterborne disease outbreaks.

EPA used data from studies performed with low pressure mercury vapor lamps on water with turbidity representative of filtered water to derive the UV dose values in Table IV.D–5. Studies with low pressure mercury vapor lamps were selected because they allow the UV dose to be accurately quantified (see USEPA 2003a for specific studies). The UV dose values in Table IV.D–5 can be applied to medium pressure mercury vapor lamps and other lamp types through UV reactor validation testing, as described in the UV Disinfection Guidance Manual. Due to the potential for particulate matter to interfere with UV disinfection, the application of these dose values is limited to post-filtration in filtered PWSs and to unfiltered PWSs.

Flow-through UV reactors deliver a distribution of doses due to variations in light intensity and particle flow path through the reactor. To best account for the dose distribution, the validation test must use a challenge microorganism to determine the degree of inactivation achieved by the UV reactor. This level of performance must then be associated to the UV dose requirements in Table IV.D–5 through known dose-response relationships for the challenge microorganism and target pathogen in order to assign disinfection credit to the UV reactor. States may approve an alternative basis for awarding UV disinfection credit.

Today's rule requires full-scale testing of UV reactors to validate the operating conditions under which the reactors can deliver a required UV dose. EPA believes this testing is necessary due to the uncertainty associated with predicting reactor disinfection performance entirely through modeling or through reduced-scale testing. Under today's rule, EPA intends UV reactor validation testing to be reactor-specific and not site-specific. This means that once a UV reactor has been validated for a range of operating conditions, the validation test results can be applied by all PWSs that will operate within those conditions without the need for retesting at each individual site.

Validation testing must account for factors that will influence the dose delivered by UV reactors during routine operation. These factors include UV absorbance, lamp fouling, lamp aging, the performance of UV intensity sensors, hydraulic flow path and residence time distributions, UV lamp failure, and reactor inlet and outlet hydraulics. The successful outcome of validation testing is the determination of acceptable operating ranges for parameters the PWSs can monitor to ensure delivery of the required UV dose during treatment. The specific parameters will vary depending on the reactor control strategy. In all cases, however, PWSs must monitor UV intensity within the reactor as measured by UV sensors, the flow rate, and the status of lamps. EPA believes that any effective UV reactor control strategy will involve monitoring for these parameters.

Today's rule requires all PWSs using UV for disinfection compliance to treat

at least 95 percent of the water distributed to the public each month with UV reactors operating within validated conditions for the required UV dose. EPA views this 95 percent limit as a feasible minimum level of performance for PWSs to achieve, while ensuring the desired level of health protection is provided. For purposes of design and operation, PWSs should strive to deliver the required UV dose at all times during treatment.

EPA developed these requirements and the associated UV Disinfection Guidance Manual solely for public water systems using UV light to meet drinking water disinfection standards established under SDWA. EPA has not addressed and did not consider the extension of these requirements and guidance to other applications, including point of entry or point of use devices for residential water treatment that are not operated by public water systems to meet SDWA disinfection standards.

c. Summary of Major Comments

Public comment on the August 11, 2003 LT2ESWTR proposal supported the inclusion of UV light in the microbial toolbox for Cryptosporidium inactivation. EPA received significant comment on the UV dose tables, the use of adenovirus as the basis for virus UV dose requirements, UV compliance standards for filtered systems, and safety factors associated with draft guidance. These comments and EPA's responses are summarized as follows.

Commenters generally supported the proposed UV dose values for Cryptosporidium and Giardia lamblia inactivation and recommended that EPA incorporate these values into the final rule. Several commenters requested that EPA provide values for 3.5-, 4.0- or higher log inactivation of Cryptosporidium and Giardia lamblia because available dose-response data include this range. Due to factors like tailing and censoring in the underlying dose-response data, some commenters stated that the proposed UV dose values are conservative and advised EPA to consider this conservatism when recommending additional safety factors in guidance.

In response, EPA has extended the UV dose table in today's rule to cover 3.5- and 4.0-log Cryptosporidium and Giardia lamblia inactivation. None of EPA's regulations require inactivation of Cryptosporidium or Giardia lamblia above these levels, so EPA has not established UV dose requirements for inactivation above 4-log. EPA believes that the statistical analysis used to determine the required UV doses appropriately accounts for variability, tailing, and censoring in the underlying dose-response data. However, the required UV dose values do not account for bias and uncertainty associated with UV reactor validation and monitoring, which are addressed in guidance.

Several commenters were concerned with the use of adenovirus to set UV dose requirements for virus inactivation because the resulting dose values are several times higher than typical UV doses for drinking water disinfection. These high dose values impact the feasibility of PWSs using UV to fully meet virus treatment requirements, which will hinder the use of UV to reduce DBPs and for point-of-entry treatment. Commenters requested that EPA consider waterborne viruses that are more UV-sensitive, such as rotavirus or hepatitus, when setting UV dose requirements. Commenters noted that adenovirus commonly causes infections of the lung or eye, which are not transmitted through water consumption, and that no drinking water outbreaks associated with adenovirus have been reported in the United States.

EPA recognizes that the UV doses for virus inactivation in today's rule are relatively high and that this will limit the degree to which PWSs can use UV for virus treatment. Based on occurrence and health effects, however, EPA continues to believe that UV dose requirements should be protective for adenovirus. The existing requirement for 4-log virus treatment, as established under the SWTR, applies to all waterborne viruses of public health concern in PWSs. Adenovirus is consistently found in water subject to fecal contamination and can be transmitted through consumption of or exposure to contaminated water. It is a common cause of diarrheal illness, particularly in children, and fecal shedding is prevalent in asymptomatic adults. While illness from adenovirus is typically self-limiting, severe health effects, including death, can occur. Consequently, EPA regards adenovirus as a potential health concern in PWSs and has established UV dose requirements to address it.

Many commenters recommended that EPA establish a compliance standard for the operation of UV reactors within validated conditions by filtered PWSs, similar to the 95 percent standard proposed for unfiltered PWSs. Commenters were concerned that without a clear compliance standard in the rule, filtered PWSs would be held to inconsistent and unclear standards, which would impede the design and implementation of UV systems. Some commenters recommended that filtered PWSs by held to the same 95 percent standard as unfiltered PWSs, while others recommended a lower 90 percent standard on the basis that filtered PWSs have more barriers of protection.

EPA agrees that establishing a clear compliance standard for the use of UV to meet inactivation requirements is appropriate. For filtered PWSs using UV to meet microbial treatment requirements, today's final rule requires at least 95 percent of the water distributed to consumers to be treated by UV reactors operating within validated conditions. This is the same standard that applies to unfiltered PWSs. EPA believes that a 95th percentile standard is feasible for all PWSs and represents the minimum level of performance that should be achieved. During routine operation, PWSs should endeavor to maintain UV reactors within validated conditions for the required UV dose at all times.

E. Disinfection Benchmarking for Giardia lamblia and Viruses

1. Today's Rule

The purpose of disinfection benchmarking under today's rule is to ensure that PWSs maintain protection against microbial pathogens as they implement the Stage 2 DBPR and LT2ESWTR. If a PWS proposes to make a significant change in disinfection practice, the PWS must perform the following:

- Develop a disinfection profile for Giardia lamblia and viruses. A disinfection profile consists of documenting Giardia lamblia and virus log inactivation levels at least weekly over a period of at least one year. PWSs that operate for less than one year must profile only during the period of operation. The calculated log inactivation levels must include the entire treatment plant and must be based on operational and water quality data, such as disinfectant residual concentration(s), contact time(s), temperature(s), and, where necessary, pH. PWSs may create profiles by conducting new weekly (or more frequent) monitoring and/or by using previously collected data. A PWS that created a Giardia lamblia disinfection profile under the IESWTR or LT1ESWTR may use the operational data collected for the Giardia lamblia profile to create a virus disinfection profile.
- Calculate a disinfection benchmark, using the following procedure: (1) Determine the calendar month with the lowest log inactivation; (2) The lowest month becomes the critical period for that year; (3) If acceptable data from

multiple years are available, the average of critical periods for each year becomes the benchmark; (4) If only one year of data is available, the critical period for that year is the benchmark.

- Notify the State before implementing the significant change in disinfection practice. The notification to the State must include a description of the proposed change, the disinfection profiles and inactivation benchmarks for Giardia lamblia and viruses, and an analysis of how the proposed change will affect the current inactivation benchmarks.

For the purpose of these requirements, significant changes in disinfection practice are defined as (1) moving the point of disinfection (this is not intended to include routine seasonal changes already approved by the State), (2) changing the type of disinfectant, (3) changing the disinfection process, or (4) making other modifications designated as significant by the State. The Disinfection Profiling and Benchmarking Guidance Manual provides information to PWSs and States on the development of disinfection profiles, identification and evaluation of significant changes in disinfection practices, and considerations for setting an alternative benchmark (USEPA 1999d).

2. Background and Analysis

A goal in the development of rules to control microbial pathogens and disinfection byproducts (DBPs) is the balancing risks between these two classes of contaminants. EPA established disinfection profiling and benchmarking under the IESWTR and LT1ESWTR, based on a recommendation by the Stage 1 M–DBP Advisory Committee, to ensure that PWSs maintained adequate protection against pathogens as they reduced risk from DBPs. EPA is extending profiling and benchmarking requirements to the LT2ESWTR for the same objective.

Some PWSs will make significant changes in their current disinfection practice to meet TTHM and HAA5 requirements under the Stage 2 DBPR and to provide additional treatment for Cryptosporidium under the LT2ESWTR. To ensure that these PWSs maintain disinfection that is effective against a broad spectrum of microbial pathogens, EPA believes that PWSs and States should evaluate the effects of significant changes in disinfection practice on current microbial treatment levels. Disinfection profiling and benchmarking serves as a tool for making such evaluations.

The August 11, 2003 LT2ESWTR proposal included disinfection profiling and benchmarking requirements. Under the proposal, profiling for Giardia lamblia and viruses was required if a PWS was required to monitor for Cryptosporidium or, in the case of small PWSs, exceeded 80 percent of the TTHM or HAA5 MCL based on a locational running annual average. Under this approach, most large PWSs and a significant fraction of small PWSs were required to develop profiles. The proposal also included a schedule for disinfection profile development. Those PWSs that developed profiles were then required to calculate a disinfection benchmark and notify the State if they proposed to make a significant change in disinfection practice.

In today's final rule, EPA has significantly modified the applicability requirements for disinfection profiling. PWSs are only required to develop a disinfection profile if they propose to make a significant change in disinfection practice after completing the first round of source water monitoring. EPA has made this change from the proposal because under the LT2ESWTR and Stage 2 DBPR, most PWSs will not be required to make significant changes to their disinfection practice. Consequently, most PWSs will not need a disinfection profile. EPA believes that disinfection profiling requirements should be targeted to those PWSs that will make significant disinfection changes.

EPA has also eliminated the scheduling requirements for development of the disinfection profile in order to provide more flexibility to PWSs and States. Today's rule only requires that PWSs notify States prior to making a significant change in their disinfection practice and that this notification include the disinfection profiles and benchmarks, along with an analysis of how the proposed change will affect the current benchmarks. EPA believes that PWSs should collect the operational data needed to develop disinfection profiles, such as disinfectant residual, water temperature, and flow rate, as part of routine practice. PWSs that do not have current disinfection profiles should record this operational information at least weekly for one year so that they can use it to develop disinfection profiles if required.

Today's rule retains the proposed requirement that when disinfection profiling is required, PWSs must develop profiles for both Giardia lamblia and viruses. EPA believes that profiling for both target pathogens is appropriate because the types of treatment changes that PWSs will make to comply with the Stage 2 DBPR or LT2ESWTR could lead to a significant change in the inactivation level for one pathogen but not the other. For example, a PWS that switches from chlorine to UV light to meet Giardia lamblia inactivation requirements is likely to maintain a high level of treatment for this pathogen. The level of treatment for viruses, however, may be significantly reduced. In general, viruses are much more sensitive to chlorine than Giardia but are more resistant to UV. The situation for a PWS switching to microfiltration is similar. The same operational data are used to develop disinfection profiles for both Giardia lamblia and viruses.

As was the case with the IESWTR and LT1ESWTR, the disinfection benchmark under today's rule is not intended to function as a regulatory standard. Rather, the objective of these provisions is to facilitate interactions between the States and PWSs to assess the impact on microbial risk of proposed changes to disinfection practice. Final decisions regarding levels of disinfection for Giardia lamblia and viruses beyond the minimum required by regulation will continue to be left to the States and PWSs. To ensure that the level of treatment for both protozoan and viral pathogens is appropriate, States and PWSs should consider site-specific factors such as source water contamination levels and the reliability of treatment processes.

3. Summary of Major Comments

EPA received significant public comment on disinfection profiling and benchmarking requirements in the August 11, 2003 proposal. A few commenters supported the proposed requirements but most raised concerns with the burden and usefulness of disinfection profiling and requested greater flexibility. These comments and EPA's responses are summarized as follows.

Commenters stated that disinfection profiling diverts PWS and State resources from other public health protection activities and presents an incomplete picture of the information that should be considered when evaluating disinfection changes. Further, some States can only require the level of treatment specified in regulations (e.g., the SWTR, IESWTR, LT1ESWTR) and cannot use a disinfection benchmark to enforce a higher treatment standard. Some commenters also disagreed with requiring a disinfection profile for viruses, since current disinfection practices targeting Giardia lamblia typically achieve much greater virus inactivation than required.

To address these concerns, commenters requested that profiling only be required for PWSs prior to switching disinfectants or that States be allowed to grant waivers from disinfection profiling requirements. Commenters also recommended that States be given flexibility to determine the appropriate time for PWSs to develop disinfection profiles, if necessary. In regard to virus profiling, some commenters suggested that it only be required for PWSs that have not developed profiles for Giardia lamblia or that are switching disinfectants to UV.

In response, EPA has modified the proposed requirements for disinfection profiling and benchmarking from the proposal to significantly reduce the burden on PWSs and States. In today's final rule, profiling is only required for PWSs that propose to make a significant change in disinfection practice. EPA projects that most PWSs will not be required to make treatment changes to comply with the LT2ESWTR and Stage 2 DBPR and, as a result, will not be required to develop disinfection profiles. Further, today's rule gives PWSs and States flexibility to determine the timing for developing disinfection profiles and only requires that the profiles and benchmarks be included in a notification to the State before a PWS implements a significant change in disinfection practice. For PWSs that have not developed disinfection profiles, EPA recommends recording the necessary operational data at least weekly over one year so that a profile can be prepared if needed.

For PWSs that propose to make a significant change in disinfection practice, today's rule maintains the proposed requirement for a disinfection profile for viruses. EPA recognizes that current disinfection practices with chlorine typically achieve far more virus inactivation than required. However, the types of treatment changes that PWSs will make to comply with the Stage 2 DBPR or LT2ESWTR, such as implementing UV or microfiltration, are likely to maintain high levels of treatment for Giardia lamblia but may result in a significant decrease in treatment for viruses. Consequently, EPA believes that States and PWSs should consider whether such a decrease in virus treatment will occur when evaluating proposed treatment changes.

Moreover, developing a virus disinfection profile does not require the collection of operational data beyond that necessary to develop a Giardia lamblia disinfection profile. Therefore, today's rule allows PWSs to use previously developed Giardia lamblia disinfection profiles and allows the operational data that underlie the Giardia lamblia profile to be used for a virus disinfection profile.

F. Requirements for Systems With Uncovered Finished Water Storage Facilities

1. Today's Rule

Today's rule requires PWSs that store treated water in an open reservoir (i.e., use uncovered finished water storage facilities) to do either of the following:

- Cover the finished water storage facility; or
- Treat the discharge of the uncovered finished water storage facility that is distributed to consumers to achieve inactivation and/or removal of 4-log virus, 3-log Giardia lamblia, and 2-log Cryptosporidium.

PWSs must notify the State if they use uncovered finished water storage facilities no later than April 1, 2008. PWSs must either meet the requirements of today's rule for covering or treating each facility or be in compliance with a State-approved schedule for meeting these requirements no later than April 1, 2009.

Today's rule revises the definition of an uncovered finished water storage facility as follows: uncovered finished water storage facility is a tank, reservoir, or other facility used to store water that will undergo no further treatment to reduce microbial pathogens except residual disinfection and is directly open to the atmosphere.

2. Background and Analysis

The requirements in today's rule for PWSs that use uncovered finished water storage facilities (open reservoirs) are based on an assessment of the types and sources of contaminants in open reservoirs, the efficacy and feasibility of regulatory approaches to reduce risks from this contamination, and comments on the August 11, 2003 proposal. The following discussion summarizes this assessment.

a. *Types and sources of contaminants in open reservoirs.* The storage of treated drinking water in open reservoirs can lead to significant water quality degradation and health risks to consumers (USEPA 1999e). Examples of such water quality degradation include increases in algal cells, coliform bacteria, heterotrophic plate count bacteria, turbidity, particulates, DBPs, metals, taste and odor, insect larvae, Giardia, Cryptosporidium, and nitrate (USEPA 1999e). Contamination of open reservoirs occurs through surface water runoff, bird and animal wastes, human activity, algal growth, insects and fish, and airborne deposition. Additional information on these sources of contamination follows.

If a reservoir receives surface water runoff, the SWTR requires that it be treated as raw water storage, rather than a finished water reservoir (40 CFR 141.70(a)). Nevertheless, many uncovered finished water reservoirs have been found to be affected by surface water runoff, which may include agricultural fertilizers, pesticides, microbial pathogens, automotive fluids and residues, sediment, nutrients, natural organic matter, and metals (USEPA 1999e, LeChevallier et al. 1997).

Birds are a significant cause of contamination in open reservoirs, and bird feces may contain coliform bacteria, viruses, and other human pathogens, including vibrio cholera, Salmonella, Mycobacteria, Typhoid, Giardia, and Cryptosporidium (Geldreich and Shaw 1993). Birds can ingest pathogens at landfills or wastewater treatment plants prior to visiting a reservoir and have been shown to carry and pass infectious Cryptosporidium parvum (Graczyk et al. 1996). Five to twenty percent of birds are estimated to be periodically infected with human pathogens like Salmonella (USEPA 1999e). A 1993 Salmonella outbreak in Gideon, MO that resulted in seven deaths was traced to pigeons roosting in a finished water storage tank.

Animals that are either known or suspected to contaminate open reservoirs include dogs, cats, deer, rats, mice, opossums, squirrels, muskrats, raccoons, beavers, rabbits, and frogs. Some animals are infected with human pathogens like Cryptosporidium, which can be discharged to the reservoirs in feces or transmitted by direct contact between animals and the water (Fayer and Unger 1986, Current 1986, USEPA 1999e).

Open reservoirs are exposed to contamination through human activities. Pesticides and fertilizers can enter open reservoirs through runoff and airborne drifts from spray applications. Swimming in reservoirs can result in pathogens being passed from the feces, shedded skin, and mucus membranes of infected persons. PWSs routinely find a great variety of items that have been thrown into open reservoirs, despite the use of high fences and set-back distances. Such items include baby carriages, beer bottles, bicycles, bullets, dead animals, dog waste bags, fireworks, garbage cans, a pay phone, shoes, and shovels (USEPA 1999e). These items are a potential source of pathogens and toxic substances and clearly indicate the

susceptibility of open reservoirs to intentional contamination.

Algal growth is common in open reservoirs and can lead to aesthetic problems like color, taste, and odor, and may generate cyanobacterial toxins, which cause headaches, fever, diarrhea, abdominal pain, nausea, and vomiting. In addition, algae can increase other contaminants like DBPs by increasing biomass within reservoirs, and corrosion products like lead, through causing significant pH fluctuations. Algae have been shown to shield bacteria from the effects of disinfection (Geldreich and Shaw 1993).

Open reservoirs may be infested with the larvae of insects such as midge flies, water fleas, and gnats, which can be carried through the distribution system from the reservoir (USEPA 1999e). Chlorination is ineffective against midge fly larvae. Fly outbreaks may increase the presence of insect-eating birds, which present another source of contamination as described earlier. Some open finished water reservoirs have been found to support fish populations.

Open reservoirs also are subject to airborne deposition of contaminants, such as industrial pollutants, automobile emissions, pollen, dust, particulate matter, and bacteria. Deposition occurs during all types of weather conditions, but is likely to be accelerated during precipitation events as air pollutants are transported from the air column above the reservoir by rain or snow.

b. *Regulatory approaches to reduce risk from contamination in open reservoirs.* For many decades, public health agencies and professional associations like the American Public Health Association, the U.S. Public Health Service, and the American Water Works Association have recommended that all finished water reservoirs be covered (USEPA 1999e). In the IESWTR and LT1ESWTR, EPA prohibited the construction of new uncovered finished water reservoirs (40 CFR 141.170(c) and 141.511). These regulations did not address existing uncovered finished water reservoirs, however. In the preamble to the IESWTR, EPA stated that a requirement to cover existing reservoirs would be considered when data to develop national cost estimates were available.

EPA has now collected the necessary data to estimate costs associated with regulatory control strategies for uncovered finished water reservoirs. The August 11, 2003 LT2ESWTR proposal included three options for PWSs with uncovered finished water reservoirs to reduce risk: (1) cover the reservoir, (2) treat the discharge to achieve 4-log virus inactivation, or (3) implement a State-approved risk mitigation plan (USEPA 2003a). These options reflected recommendations from the Stage 2 M–DBP Advisory Committee (USEPA 2000a). Today's final rule includes the first option to cover, modifies the second option to also require 3-log Giardia and 2-log Cryptosporidium treatment, and does not establish an option for a risk mitigation plan. The following discussion describes the basis for these changes.

As described earlier, studies have shown that small mammals and birds that live near water may be infected with Cryptosporidium and Giardia and may shed infectious oocysts and cysts into the water (Graczyk et al. 1996, Fayer and Unger 1986, Current 1986). LeChevallier et al. (1997) evaluated Cryptosporidium and Giardia levels in six uncovered finished water reservoirs. The geometric mean concentration of Cryptosporidium was 1.2 oocysts/100 L in the inlet samples and 8.1 oocysts/100 L in the effluent samples (i.e., 600 percent increase in the reservoir). For Giardia, the geometric mean concentrations in the inlet and effluent samples were 1.9 and 6.1 cysts/100 L, respectively (i.e., 200 percent increase in reservoir).

Most, if not all, PWSs would treat to achieve 4-log virus inactivation with chlorine. Based on EPA guidance, the dose of chlorine necessary for 4-log virus inactivation would not achieve even 0.5-log Giardia inactivation and would produce no inactivation of Cryptosporidium (USEPA 1991b). Consequently, PWSs treating for viruses in open reservoirs, as proposed, would provide very little protection against contamination by Giardia and Cryptosporidium.

Due to the demonstrated potential for contamination by Giardia and Cryptosporidium in open reservoirs and the ineffectiveness of virus treatment against these pathogens, today's rule requires PWSs to treat for Giardia and Cryptosporidium in addition to viruses if they do not cover their finished water reservoirs. Specifically, today's rule specifies the same baseline treatment as required for a raw unfiltered source, which is 4-log virus, 3-log Giardia, and 2-log Cryptosporidium reduction.

EPA believes that requiring treatment for viruses, Giardia, and Cryptosporidium in uncovered finished water reservoirs is consistent with SDWA section 1412(b)(7)(A), which authorizes the use of a treatment technique to prevent adverse health effects to the extent feasible if measuring the contaminant is not feasible. Monitoring for these pathogens at the very low levels that would cause public health concern and at the frequency necessary to detect contamination events is not feasible with available analytical methods. EPA has determined that with the availability of technologies like UV, treating for Giardia, Cryptosporidium, and viruses is feasible for all PWS sizes.

Today's rule does not allow PWSs to implement a risk mitigation plan as an alternative to covering a reservoir or treating the discharge because EPA does not believe that a risk mitigation plan would provide equivalent public health protection. Consequently, a risk mitigation plan would not meet the statutory provision for a treatment technique to prevent adverse health effects from pathogens like Giardia and Cryptosporidium to the extent feasible (SDWA section 1412(b)(7)(A)).

As discussed earlier, open reservoirs are subject to contamination from many sources, including runoff, birds, animals, humans, algae, insects, and airborne deposition. Control measures can provide a degree of protection against some of these sources (e.g., bird deterrent wires, security fences with setback distances). All PWSs are significantly constrained, however, in the degree to which they can implement such measures with existing open reservoirs due to factors like the size of the reservoir, the location of the reservoir (e.g., within residential communities or parks), and the existing infrastructure. For example, many open finished water reservoirs are impacted by runoff, despite the fact that this has been prohibited for many years under existing regulations (USEPA 1999e). EPA has concluded that implementing control measures that would be highly effective against all sources of contamination of open reservoirs would not be feasible for PWSs. Accordingly, today's rule does not allow this option.

c. *Definition of uncovered finished water storage facility.* The IESWTR established the following definition for an uncovered finished water storage facility: uncovered finished water storage facility is a tank, reservoir, or other facility used to store water that will undergo no further treatment except residual disinfection and is open to the atmosphere.

In the August 11, 2003, proposed LT2ESWTR, EPA requested comment on whether this definition should be revised. EPA was concerned that it would not include certain cases in which water is stored in an open reservoir after a PWS completes treatment to reduce microbial

pathogens. Such a case would be a PWS that applies a corrosion inhibitor to the effluent of an open reservoir where water is stored after filtration and primary disinfection. In this case, the PWS could claim that the corrosion inhibitor constitutes additional treatment and, consequently, the open reservoir does not meet EPA's definition of an uncovered finished water storage facility. However, the water stored in the open reservoir would be subject to microbial contamination from the sources described in this section and would undergo no further treatment for this contamination.

Today's rule revises the definition of an uncovered finished water storage facility in two ways: (1) The phrase ''to reduce microbial pathogens'' is inserted following the word ''treatment;'' and (2) the word ''directly'' is inserted prior to ''open to the atmosphere.'' The first change ensures that an open reservoir where water is stored after a PWS has completed filtration (where required) and primary disinfection will be appropriately classified as an uncovered finished water storage facility. Whether a PWS applies corrosion control or other treatment to maintain water quality in the distribution system will not affect this determination.

The second change clarifies that covered reservoirs with air vents or overflow lines are not uncovered finished water storage facilities. Such air vents and overflow lines are open to the atmosphere but are usually hooded or screened to prevent contamination of the water. Consequently, these reservoirs are not directly open to the atmosphere and are not subject to the requirements of today's rule for uncovered finished water storage facilities.

3. Summary of Major Comments

EPA received significant public comment on requirements for uncovered finished water storage facilities in the August 11, 2003 proposal. Major issues raised by commenters include whether to require all reservoirs to be covered, requiring treatment for Giardia and Cryptosporidium, support for the proposed options, and revising the definition of an uncovered finished water storage facilities. A summary of these comments and EPA's responses follows.

Several commenters recommended that EPA require all finished water reservoirs to be covered. These commenters stated that making an uncovered reservoir equal in quality to a covered reservoir is not possible—open reservoirs will always be contaminated by fecal material from birds and small mammals, as well as increased DBPs due to algae and other aquatic organisms, airborne contaminants, and sediment stirred up by wind. Commenters were also concerned that uncovered reservoirs are a major vulnerability for PWS security (i.e., intentional contamination). Some commenters cited the fact that there are hundreds of thousands of covered finished water reservoirs in comparison to approximately 100 uncovered finished water reservoirs as evidence that the public health risks of open reservoirs are widely recognized.

EPA agrees that storing treated water in open reservoirs presents a risk to public health. With today's final rule, EPA expects that many PWSs will cover or eliminate uncovered finished water reservoirs. For reservoirs where covering is not feasible, EPA believes that treating the water for Giardia, Cryptosporidium, and viruses will provide protection against the range of pathogens likely to contaminate the reservoir.

Many commenters supported requiring treatment for Giardia and Cryptosporidium for PWSs that treat the reservoir discharge. Commenters stated that reservoirs should either be covered or treated as unfiltered sources (meaning 3-log Giardia, 2-log Cryptosporidium, and 4-log virus treatment). The LeChevallier et al. (1997) study was cited as demonstrating increases in Giardia and Cryptosporidium in uncovered finished water reservoirs, and commenters noted that treatment for viruses would not be effective against these protozoa. EPA agrees with these comments and today's rule requires treatment for Giardia and Cryptosporidium, as well as viruses, by PWSs that do not cover their reservoirs.

Some commenters expressed support for the proposed options, including allowing risk mitigation plans as an adequate remedy for an uncovered reservoir. These commenters characterized the proposal as providing reasonable alternatives to the substantial costs involved in covering reservoirs or providing alternative storage. Commenters stated that strategies included in a risk management plan could address the range of microorganisms for which treatment is necessary, depending on site-specific circumstances.

EPA recognizes that covering or finding alternative storage for uncovered finished water reservoirs can be costly. While EPA believes that covering finished water reservoirs is the most effective approach to protecting public health, today's rule allows PWSs to provide treatment for Giardia, Cryptosporidium, and viruses as a feasible alternative. As described earlier, EPA does not believe that providing treatment only for viruses, as proposed, would be protective against the range of pathogens that contaminate open reservoirs. Further, EPA has concluded that implementing a risk mitigation plan that would provide equivalent protection to covering or treating a reservoir is not feasible. This is due to the many potential sources of contamination and the significant limitations that all PWSs have in the control measures they can implement for existing open reservoirs.

Commenters supported revising the definition of uncovered finished water storage facilities to include situations where PWSs apply a treatment like corrosion control to water stored in an open reservoir after the water has undergone filtration, where required, and primary disinfection. In addition, commenters recommended that EPA clarify that ''open to the atmosphere'' in the definition does not include vents and overflow lines in covered reservoirs. EPA agrees with these comments and today's rule is consistent with them.

G. Compliance Schedules

1. Today's Rule

This section specifies compliance dates for the monitoring and treatment technique requirements in today's rule. As described in sections IV.A through IV.F of this preamble, today's rule requires PWSs to carry out the following activities:

- Conduct initial source water monitoring on a reported schedule. PWSs may grandfather previously collected monitoring results and may elect to provide the maximum Cryptosporidium treatment level of 5.5-log for filtered PWSs or 3.0-log for unfiltered PWSs instead of monitoring.
- Determine a treatment bin classification (or mean Cryptosporidium level for unfiltered PWSs) based on monitoring results.
- For filtered PWSs in Bins 2–4 and all unfiltered PWSs, provide additional treatment for Cryptosporidium by selecting technologies from the microbial toolbox.
- Report disinfection profiles and benchmarks prior to making a significant change in disinfection practice.
- Report the use of uncovered finished water storage facilities and cover or treat the discharge of such reservoirs on a State-approved schedule.

• Conduct a second round of source water monitoring approximately six years after initial bin classification.

Compliance dates for these activities vary by PWS size. Tables IV.G–1 and IV.G–2 specify source water monitoring and treatment compliance dates for large and small PWSs, respectively. Table IV.G–3 shows compliance dates for PWSs using uncovered finished water storage facilities. Wholesale PWSs must comply with the requirements of today's rule based on the population of the largest PWS in the combined distribution system.

TABLE IV.G–1.—MONITORING AND TREATMENT COMPLIANCE DATES FOR PWSS SERVING AT LEAST 10,000 PEOPLE

Requirement	Compliance dates by PWS Size		
	PWSs serving at least 100,000 people	PWSs serving at least 50,000 but less than 100,000 people	PWSs serving at least 10,000 but less than 50,000 people
Report sampling schedule and sampling location description for initial source water monitoring for Cryptosporidium (plus E. coli and turbidity at filtered PWSs) [1, 2].	No later than July 1, 2006.	No later than January 1, 2007.	No later than January 1, 2008.
Report notice of intent to grandfather previously collected Cryptosporidium data, if applicable.			
Report intent to provide the maximum Cryptosporidium treatment level in lieu of monitoring, if applicable [1].			
Begin initial source water monitoring for Cryptosporidium (plus E. coli and turbidity at filtered PWSs) [1,2].	No later than the month beginning October 1, 2006.	No later than the month beginning April 1, 2007.	No later than the month beginning April 1, 2008.
Submit previously collected Cryptosporidium data and required documentation for grandfathering, if applicable.	No later than December 1, 2006.	No later than June 1, 2007..	No later than June 1, 2008.
Report Cryptosporidium treatment bin classification (or mean Cryptosporidium concentration for unfiltered PWSs) and supporting data for approval.	No later than the month beginning April 1, 2009.	No later than the month beginning October 1, 2009.	No later than the month beginning October 1, 2010.
Report disinfection profiles and benchmarks, if applicable.	Prior to making a significant change in disinfection practice.		
Comply with additional Cryptosporidium treatment requirements based on treatment bin classification (or mean Cryptosporidium concentration for unfiltered PWSs) [3].	No later than April 1, 2012 [3].	No later than October 1, 2013 [3].	No later than October 1, 2012 [3].
Report sampling schedule and sampling location description for second round of source water monitoring for Cryptosporidium (plus E. coli and turbidity at filtered PWSs) [1].	No later than January 1, 2015.	No later than July 1, 2015.	No later than July 1, 2016.
Report intent to provide maximum Cryptosporidium treatment level in lieu of monitoring, if applicable [1].			
Begin second round of source water monitoring for Cryptosporidium (plus E. coli and turbidity at filtered PWSs) [1].	No later than the month beginning April 1, 2015.	No later than the month beginning October 1, 2015.	No later than the month beginning October 1, 2016.
Report Cryptosporidium treatment bin classification (or mean Cryptosporidium concentration for unfiltered PWSs) and supporting data from second round of monitoring for approval.	No later than the month beginning October 1, 2017.	No later than the month beginning April 1, 2018.	No later than the month beginning April 1, 2019.
Comply with additional Cryptosporidium treatment requirements if bin classification (or mean Cryptosporidium concentration for unfiltered PWSs) changes based on second round of monitoring.	On a schedule the State approves.		

[1] PWS are not required to conduct source water monitoring if they submit a notice of intent to provide the maximum Cryptosporidium treatment level: 5.5-log for filtered PWSs or 3.0-log for unfiltered PWSs.

[2] Not required if PWS grandfathers at least 2 years of Cryptosporidium data.

[3] States may grant up to an additional 2 years for systems making capital improvements.

TABLE IV.G–2.—MONITORING AND TREATMENT COMPLIANCE DATES FOR PWSS SERVING FEWER THAN 10,000 PEOPLE

Requirement	Compliance dates
Indicator (E. coli) Monitoring Requirements for Filtered PWSs Only	
Report sampling schedule and sampling location description for initial source water monitoring for E. coli or alternative State-approved indicator [1 2].	No later than July 1, 2008.
Report notice intent to grandfather previously collected E. coli data, if applicable.	
Report intent to provide the maximum Cryptosporidium treatment level in lieu of monitoring, if applicable [1].	
Begin initial source water monitoring for E. coli [1 2]	No later than the month beginning October 1, 2008.
Report E. coli data for grandfathering, if applicable	No later than December 1, 2008.

TABLE IV.G–2.—MONITORING AND TREATMENT COMPLIANCE DATES FOR PWSS SERVING FEWER THAN 10,000 PEOPLE—Continued

Requirement	Compliance dates	
Report sampling schedule and sampling location description for second round of source water monitoring for E. coli [1].	No later than July 1, 2017.	
Report intent to provide the maximum Cryptosporidium treatment level in lieu of monitoring, if applicable [1].		
Begin second round of source water monitoring for E. coli [1].	No later than the month beginning October 1, 2017.	
Requirement	Compliance dates by monitoring option	
	PWSs monitoring twice-per-month for 1 year	PWSs monitoring monthly for 2 years
Cryptosporidium Monitoring Requirements for Filtered PWSs That Exceed Indicator (E. coli) Trigger Concentration [3] and All Unfiltered PWSs		
Report sampling schedule and sampling location description (if not reported previously) for initial source water monitoring for Cryptosporidium [1 4].	No later than January 1, 2010.	
Report notice of intent to grandfather previously collected Cryptosporidium data, if applicable.		
Begin initial source water monitoring for Cryptosporidium [1 4]	No later than the month beginning April 1, 2010.	
Submit previously collected Cryptosporidium data and required documentation for grandfathering, if applicable.	No later than June 1, 2010.	
Report Cryptosporidium treatment bin classification (or mean Cryptosporidium concentration for unfiltered PWSs) and supporting data for approval.	No later than the month beginning October 1, 2011.	No later than the month beginning October 1, 2012.
Report disinfection profiles and benchmarks, if applicable	Prior to making a significant change in disinfection practice.	
Comply with additional Cryptosporidium treatment requirements based on treatment bin classification (or mean Cryptosporidium concentration for unfiltered PWSs) [5].	No later than October 1, 2014 [5].	
Report sampling schedule sampling location description (if not reported previously) for second round of source water Cryptosporidium monitoring [1].	No later than than January 1, 2019.	
Begin second round of source water monitoring for Cryptosporidium [1].	No later than the month beginning April 1, 2019.	
Report Cryptosporidium treatment bin classification (or mean Cryptosporidium concentration for unfiltered PWSs) and supporting data from second round of monitoring for approval.	No later than the month beginning October 1, 2020.	No later than the month beginning October 1, 2021.
Comply with additional Cryptosporidium treatment requirements if bin classification (or mean Cryptosporidium concentration for unfiltered PWSs) changes based on second round of monitoring.	On a schedule the State approves.	

[1] PWS are not required to conduct source water monitoring if they submit a notice of intent to provide the maximum Cryptosporidium treatment level: 5.5-log for filtered PWSs or 3.0-log for unfiltered PWSs.
[2] Not required if PWS grandfathers at least 1 year of E. coli data.
[3] Filtered PWSs must conduct Cryptosporidium monitoring if the E. coli annual mean concentration exceeds 10/100 mL for PWSs using lake or reservoir sources or exceeds 50/100 mL for PWSs using flowing stream sources or a trigger value for an alternative State-approved indicator is exceeded.
[4] Not required if PWS grandfathers at least 1 year of twice-per-month or 2 years of monthly Cryptosporidium data.
[5] States may grant up to an additional 2 years for PWSs making capital improvements.

TABLE IV.G–3.—COMPLIANCE DATES FOR PWSS USING UNCOVERED FINISHED WATER STORAGE FACILITIES

Report the use of uncovered finished water storage facilities, if applicable.	No later than April 1, 2008.
Either comply with requirement to cover or treat uncovered finished water storage facilities or comply with State-approved schedule to meet this requirement.	No later than April 1, 2009.

2. Background and Analysis

The compliance schedule in today's final rule stems from its risk-targeted approach, wherein PWSs initially conduct monitoring to determine additional treatment requirements. A primary objective of this schedule is to ensure that PWSs provide additional treatment without delay for higher risk sources. This is especially important with a risk-targeted rule, given the significant time required for initial monitoring. However, the compliance schedule balances this objective with the need to provide PWSs and States with time to prepare for implementation activities.

SDWA section 1412(b)(10) states that a drinking water regulation shall take effect 3 years from the promulgation date unless the Administrator determines that an earlier date is practicable. Today's rule requires PWSs to begin monitoring prior to 3 years from the promulgation date. Based on EPA's assessment and recommendations of the Advisory Committee, as described in this section, EPA has determined that these monitoring start dates are practicable and appropriate.

In general, PWSs serving at least 10,000 people conduct two years of source water monitoring for Cryptosporidium (as well as E. coli and turbidity in filtered PWSs). At the conclusion of this monitoring, these PWSs have six months to analyze monitoring results and report their treatment bin classification to the State for approval. Where required, PWSs must provide the necessary level of additional Cryptosporidium treatment within three years of bin classification, though States may allow an additional two years for PWSs making capital improvements. A second round of source water monitoring must be initiated six years after initial bin classification.

For PWSs serving at least 10,000 people, the timing of monitoring and treatment activities in today's rule partially reflects recommendations by the Stage 2 M–DBP Advisory Committee and the schedule in the August 11, 2003 proposed LT2ESWTR. EPA has modified the proposed compliance schedule to stagger monitoring start dates for PWSs serving 10,000 to 99,999 people. The following discussion addresses these changes from the proposal.

The proposed rule required all PWSs serving at least 10,000 people to begin source water monitoring six months after the rule was established, as recommended by the Advisory Committee. Under today's final rule, PWSs serving at least 100,000 people maintain this schedule. The monitoring start date for PWSs serving 50,000 to 99,999 people is staggered by six months and begins 12 months after the rule is effective. For PWSs serving 10,000 to 49,999, the monitoring start date is staggered by 18 months and begins 24 months after the rule is effective. Dates to comply with additional treatment requirements are staggered accordingly.

This staggering of monitoring start dates for PWSs serving 10,000 to 99,999 people is advantageous in several respects:

- Provides more time for PWSs that have not monitored for Cryptosporidium previously to prepare for monitoring (PWSs serving at least 100,000 people monitored for Cryptosporidium under the ICR). PWSs can use this time to develop budgets, establish contracts with Cryptosporidium laboratories, identify appropriate sampling locations, and learn sampling procedures.
- Provides more time for Cryptosporidium analytical laboratories to build capacity as needed to accommodate the sample analysis needs of PWSs.
- Spreads out the transactional demand for regulatory oversight. EPA anticipates that the period of greatest transactional demand for States and EPA that oversee monitoring will be when PWSs begin monitoring. The staggered schedule will allow States and EPA to provide more assistance to individual PWSs.
- Eliminates the gap between the end of large PWS monitoring and the start of small PWS monitoring (under the proposed rule schedule, a gap of 18 months existed between the time that large PWSs completed and small PWSs started Cryptosporidium monitoring). Such a gap could create difficulties with maintaining Cryptosporidium sampling and laboratory analysis expertise to support monitoring by small PWSs.

The timing of monitoring and treatment activities in today's rule for PWSs serving fewer than 10,000 people is nearly identical to the schedule in the August 11, 2003 proposed LT2ESWTR and reflects recommendations by the Advisory Committee. The only change is allowing these PWSs the option to spread their Cryptosporidium monitoring over two years in order to facilitate budgeting for this monitoring. However, this change does not affect the treatment compliance dates for these PWSs.

Specifically, filtered PWSs serving fewer than 10,000 people initially conduct one year of source water monitoring for E. coli or an alternative indicator if approved by the State, beginning 30 months after the rule is effective. At the conclusion of this monitoring, these PWSs have six months to prepare for Cryptosporidium monitoring, if required based on their indicator monitoring results. Filtered PWSs that exceed the indicator trigger value and all unfiltered PWSs serving fewer than 10,000 people must begin Cryptosporidium monitoring 48 months after the rule is effective. This Cryptosporidium monitoring may consist of sampling twice-per-month for one year or once-per-month for two years. PWSs must report their bin classification to the State for approval within six months of the scheduled completion of Cryptosporidium monitoring.

Regardless of the Cryptosporidium sampling frequency, PWSs serving fewer than 10,000 people must comply with any additional Cryptosporidium treatment requirements within 102 months (8.5 years) after the rule is effective. States may allow an additional two years for PWSs making capital improvements. PWSs must begin a second round of source water monitoring for E. coli or an alternative State-approved indicator within 11.5 years (138 months) after the rule is effective (six years after the bin classification date for PWSs that sampled for Cryptosporidium twice-per-month during initial source water monitoring).

In summary, the compliance schedule for today's rule maintains the earliest compliance dates recommended by the Advisory Committee for PWSs serving at least 100,000 people. These PWSs serve the majority of people that consume water from surface sources. The schedule also maintains the latest compliance dates the Advisory Committee recommended, which apply to PWSs serving fewer than 10,000 people. EPA has staggered compliance schedules for PWSs between these two size categories in order to facilitate implementation of the rule.

3. Summary of Major Comments

EPA received significant public comment on the compliance schedule in the August 11, 2003 proposal. Major issues raised by commenters include providing more time for PWSs to prepare for monitoring, giving States more time to oversee monitoring, ensuring that laboratory capacity can accommodate the compliance schedule, and establishing consistent schedules for consecutive PWSs. A summary of these comments and EPA's responses follows.

Commenters were concerned that some PWSs, in particular PWSs serving 10,000 to 50,000 people, would need more than the three months allowed under the proposed rule to report sampling schedules for monitoring. In order to develop sampling schedules, PWSs must establish contracts with laboratories, which may involve using municipal procurement procedures. For smaller PWSs, budgeting for this expense may require substantial time and planning.

EPA recognizes this concern and today's final rule provides significantly more time for many PWSs to submit sampling schedules. Specifically, PWSs serving 50,000 to 99,999 people and those serving 10,000 to 49,999 people must submit sampling schedules 9 and 21 months after the rule is effective, respectively. EPA believes that these PWSs will have sufficient time to develop sampling schedules with these compliance dates. Today's rule still requires PWSs serving at least 100,000 people to submit sampling schedules 3 months after the rule is effective. Because these PWSs have monitored for Cryptosporidium previously, however,

EPA believes that this compliance date is feasible for these PWSs.

Several commenters recommended that States, rather than EPA, oversee monitoring due to States' existing relationships with and knowledge of their PWSs. Commenters were concerned that some States will not participate in early implementation activities and indicated that States would prefer monitoring to begin 24 months after rule promulgation. States need sufficient time to become familiar with the rule, train their staff, prepare primacy packages, and train PWSs.

In general, EPA would prefer that States oversee monitoring by their PWSs and will work with States to facilitate their involvement with rule implementation. Where States are unable to implement today's rule, however, EPA is prepared to oversee implementation. Moreover, EPA believes that the staggered compliance schedule in today's final rule will enhance States' ability to implement the rule.

While EPA does not consider waiting until 24 months after rule promulgation to start monitoring for all PWSs to be appropriate, most PWSs will not begin monitoring until this time or later under today's rule. Among large PWSs (*i.e.*, those serving at least 10,000 people), the majority are in the 10,000 to 49,999 person size category and these PWSs do not begin monitoring until 24 months after rule promulgation. Further, all PWSs serving fewer than 10,000 people do not begin monitoring until 30 months after rule promulgation. These smaller PWSs are likely to need the most assistance from States. By staggering monitoring start dates, today's rule also reduces the number of PWSs that will begin monitoring at any one time, when the most assistance from regulatory agencies will be required.

Many commenters were concerned that the capacity at Cryptosporidium analytical laboratories would not be sufficient for the proposed implementation schedule. Commenters noted that the proposed rule schedule had a break of 18 months between the end of large PWS Cryptosporidium monitoring and the start of small PWS Cryptosporidium monitoring and thought that this break would discourage laboratories from making investments to improve capacity. Other commenters stated that excess laboratory capacity exists and that upon indication that a final rule is imminent, commercial laboratories will hire staff to handle the expected number of samples. Laboratories will, however, need time to train analysts.

EPA recognizes the concern with ensuring that capacity at Cryptosporidium laboratories will be sufficient. Through EPA's laboratory approval program (described in section IV.K), the Agency has evaluated capacity at Cryptosporidium laboratories. Based on information provided by laboratories, EPA believes that current capacity at Cryptosporidium laboratories will be sufficient for the monitoring that PWSs serving at least 100,000 people will begin six months after the rule is effective. EPA expects that commercial laboratories will increase capacity as needed to serve the demand of smaller PWSs that begin monitoring later. Approximately six months are required to train Cryptosporidium analysts. Consequently, the staggered compliance schedule should allow time for laboratories to hire and train staff as necessary. In addition, with the compliance schedule in today's final rule, no break exists between the time that large PWSs end and small PWSs begin Cryptosporidium monitoring. Thus, EPA has eliminated this potential disincentive to laboratories investing in capacity.

However, EPA will continue to monitor laboratory capacity and the ability of PWSs to contract with laboratories to meet their monitoring requirements under the LT2ESWTR. The Agency will assist with implementation of the rule to help maximize the use of available laboratory capacity by PWSs. If evidence emerges during implementation of the rule that PWSs are experiencing problems with insufficient laboratory capacity, the Agency will undertake appropriate action at that time.

In regard to consecutive PWSs (*i.e.*, PWSs that buy and sell treated water), commenters recommended that compliance schedules in the Stage 2 DBPR and LT2ESWTR should be consistent. Some commenters also suggested that where a small PWS sells water to a large PWS, the small PWS should comply on the large PWS schedule. In response, today's final rule requires PWSs that sell treated drinking water to other PWSs to comply according to the schedule that applies to the largest PWS in the combined distribution system. This approach will ensure that PWSs have the same compliance schedule under both the LT2ESWTR and Stage 2 DBPR.

H. Public Notice Requirements

1. Today's Rule

Today's rule establishes the following public notice requirements:

- For violations of treatment technique requirements, which today's rule establishes for Cryptosporidium treatment and for covering or treating uncovered finished water reservoirs, PWSs must issue a Tier 2 public notice and must use existing health effects language (except as provided below) for microbiological contaminant treatment technique violations, as stated in 40 CFR 141 Subpart Q, Appendix B.
- For violations of monitoring and testing procedure requirements, including the failure to collect one or two source water Cryptosporidium samples, PWSs must issue a Tier 3 public notice. If the State determines that a PWS has failed to collect three or more Cryptosporidium samples, the PWS must provide a Tier 2 special public notice. Violations for failing to monitor continue until the State determines that the PWS has begun sampling on a revised schedule that includes dates for collection of missed samples. This schedule may also include a revised bin determination date where necessary.
- PWSs must report their bin classification no later than six months after the end of the scheduled monitoring period (specific dates in section IV.G.). Failure by a PWS to collect the required number of Cryptosporidium samples to report its bin classification by the compliance date is a treatment technique violation and the PWS must provide a Tier 2 public notice. The treatment technique violation persists until the State determines that the PWS is implementing a State-approved monitoring plan to allow bin classification or will install the highest level of treatment required under the rule. If the PWS has already provided a Tier 2 special public notice for missing 3 sampling dates and is successfully meeting a State-approved schedule for sampling and bin determination, it need not provide a second Tier 2 notice for missing the bin determination deadline in today's rule.

2. Background and Aalysis

In 2000, EPA published the Public Notification Rule (65 FR 25982, May 4, 2000) (USEPA 2000b), which revised the general public notification regulations for PWSs in order to implement the public notification requirements of the 1996 SDWA amendments. This regulation established the requirements that PWSs must follow regarding the form, manner, frequency, and content of a public notice. Public notification of violations is an integral part of the public health protection and consumer right-to-know

provisions of the 1996 SDWA Amendments.

Owners and operators of PWSs are required to notify persons served when they fail to comply with the requirements of a NPDWR, have a variance or exemption from the drinking water regulations, or are facing other situations posing a risk to public health. The public notification requirements divide violations into three categories (Tier 1, Tier 2 and Tier 3) based on the seriousness of the violations, with each tier having different public notification requirements.

EPA has limited its list of violations and situations routinely requiring a Tier 1 notice to those with a significant potential for serious adverse health effects from short term exposure. Tier 1 violations contain language specified by EPA that concisely and in non-technical terms conveys to the public the adverse health effects that may occur as a result of the violation. States and water utilities may add additional information to each notice, as deemed appropriate for specific situations. A State may elevate to Tier 1 other violations and situations with significant potential to have serious adverse health effects from short-term exposure, as determined by the State.

Tier 2 public notices address other violations with potential to have serious adverse health effects on human health. Tier 2 notices are required for the following situations:

- All violations of the MCL, maximum residual disinfectant level (MRDL) and treatment technique requirements, except where a Tier 1 notice is required or where the State determines that a Tier 1 notice is required; and
- Failure to comply with the terms and conditions of any existing variance or exemption. Tier 3 public notices include all other violations and situations requiring public notice, including the following situations:
- A monitoring or testing procedure violation, except where a Tier 1 or 2 notice is already required or where the State has elevated the notice to Tier 1 or 2; and
- Operation under a variance or exemption.

The State, at its discretion, may elevate the notice requirement for specific monitoring or testing procedures from a Tier 3 to a Tier 2 notice, taking into account the potential health impacts and persistence of the violation.

As part of the IESWTR, EPA established health effects language for violations of treatment technique requirements for microbiological contaminants. EPA believes this language, which was developed with consideration of Cryptosporidium health effects, is appropriate for violations of some Cryptosporidium treatment requirements under the LT2ESWTR. However, for persistent monitoring violations and missing the deadline for bin determination, EPA is promulgating alternative language that better informs consumers of the nature and potential health consequences of the violation.

As described in section IV.C, EPA proposed automatically classifying PWSs in the highest treatment bin (Bin 4) if they fail to complete required monitoring. For today's final rule, EPA has determined that providing more flexibility to States in dealing with PWSs that fail to monitor is appropriate. EPA also believes, however, that responses to monitoring failures must reasonably ensure that PWSs complete monitoring as required to determine a bin classification within the compliance date, or as soon thereafter as possible. Moreover, consistent with the public health protection and consumer right-to-know provisions of the 1996 SDWA Amendments, consumers should be informed of these monitoring failures.

Instead of the proposed automatic Bin 4 classification for monitoring failures under today's rule, PWSs must provide a Tier 3 public notice for monitoring violations including up to two missed Cryptosporidium samples. If a PWS misses three or more Cryptosporidium samples (other than the specifically exempted situations described in section IV.A.1.c), this persistent violation requires a Tier 2 public notice. This elevated public notice level reflects significant concern that persistent failure to collect required samples will result in the PWS being unable to determine its Cryptosporidium treatment bin classification and the corresponding required treatment level by the compliance date.

Further, if a PWS is unable to determine a bin classification by the compliance date due to failure to collect the required number of Cryptosporidium samples, this is a treatment technique violation that also requires a Tier 2 public notice, unless the system is already complying with an alternate State-approved schedule for monitoring and bin determination. A PWS that does not determine its bin classification by the required date may not be able to comply with the Cryptosporidium treatment technique requirements of today's rule by the required date and provide the appropriate level of public health protection.

3. Summary of Major Comments

In the August 11, 2003, proposal, EPA requested comment on whether violations of the treatment requirements for Cryptosporidium under the LT2ESWTR should require a Tier 2 public notice and whether the proposed health effects language is appropriate (USEPA 2003a). Most commenters supported requiring a Tier 2 public notice for violations of Cryptosporidium treatment requirements under the LT2ESWTR and agreed that no new health effects language is needed for this notification. One commenter stated that a failure to meet Cryptosporidium removal requirements under LT2ESWTR should require Tier 1 public notice.

Today's final rule reflects the views of most commenters and is consistent with existing regulations in requiring a Tier 2 public notice for Cryptosporidium treatment technique violations. A State may elevate a violation to Tier 1 if the State determines that the violation creates significant potential for serious adverse health effects from short-term exposure.

Another commenter agreed that Tier 2 notice was appropriate but recommended that the LT2ESWTR and any associated guidance be more explicit as to when a treatment technique violation occurs with the use of microbial toolbox options. As described in section IV.D, EPA has stated in today's final rule that failure by a PWS in any month to demonstrate treatment credit with microbial toolbox options equal to or greater than its Cryptosporidium treatment requirements is a treatment technique violation. This violation lasts until the PWS demonstrates that it is meeting criteria for sufficient treatment credit to satisfy its Cryptosporidium treatment requirements.

I. Reporting Source Water Monitoring Results

This section presents specific reporting requirements that apply to source water monitoring under today's rule, including EPA's data system for reporting and reviewing monitoring results. For related requirements, see section IV.A for monitoring parameters frequency, section IV.J for required analytical methods, and section IV.K for approved laboratories. General reporting requirements under today's rule and associated compliance dates are shown in section IV.G.

1. Today's Rule

PWSs must report results from the required source water monitoring

described in section IV.A no later than 10 days after the end of the first month following the month when the sample is collected. For Cryptosporidium analyses, PWSs must report the data elements specified in Table IV.I–1. For samples in which at least 10 L is filtered and all of the sample volume is analyzed, only the sample volume filtered and the number of oocysts counted must be reported. Table IV.I–2 presents the data elements that PWSs must report for E. coli and turbidity analyses. PWSs, or approved laboratories acting as the PWSs' agents, must retain results from Cryptosporidium and E. coli monitoring until 36 months after bin determination for the particular round of monitoring.

TABLE IV.I–1.—CRYPTOSPORIDIUM DATA ELEMENTS TO BE REPORTED

Data element	Reason for data element
Identifying information:	
PWSID	Needed to associate plant with public water system.
Facility ID	Needed to associate sample result with facility.
Sample collection point	Needed to associate sample result with sampling point.
Sample collection date	Needed to determine that utilities are collecting samples at the frequency required.
Sample type (field or matrix spike) [1]	Needed to distinguish field samples from matrix samples for recovery calculations.
Sample results:	
Sample volume filtered (L), to nearest ¼ L [2]	Needed to verify compliance with sample volume requirements.
Was 100% of filtered volume examined? [3]	Needed to calculate the final concentration of oocysts/L and determine if volume analyzed requirements are met.
Number of oocysts counted	Needed to calculate the final concentration of oocysts/L.

[1] For matrix spike samples, sample volume spiked and estimated number of oocysts spiked must be reported. These data are not required for field samples.

[2] For samples in which <10 L is filtered or <100% of the sample volume is examined, the number of filters used and the packed pellet volume must also be reported to verify compliance with LT2ESWTR sample volume analysis requirements. These data are not required for most samples.

[3] For samples in which <100% of sample is examined, the volume of resuspended concentrate and volume of this resuspension processed through IMS must be reported to calculate the sample volume examined. These data are not required for most samples.

TABLE IV.I–2.—E. COLI AND TURBIDITY DATA ELEMENTS TO BE REPORTED

Data element	Reason for collecting data element
Identifying Information:	
PWS ID	Needed to associate analytical result with public water system.
Facility ID	Needed to associate plant with public water system.
Sample collection point	Needed to associate sample result with sampling point.
Sample collection date	Needed to determine that utilities are collecting samples at the frequency required.
Analytical method number	Needed to associate analytical result with analytical method.
Method Type	Needed to verify that an approved method was used and call up correct web entry form.
Source water type	Needed to assess Cryptosporidium indicator relationships.
E. coli/100 mL	Sample result (although not required, the laboratory also will have the option of entering primary measurements for a sample into the LT2ESWTR internet-based database to have the database automatically calculate the sample result).
Turbidity Information:	
Turbidity result	Needed to assess Cryptosporidium indicator relationships.

PWSs serving at least 10,000 people must submit sampling schedules (described in section IV.A) and monitoring results for the initial source water monitoring to EPA electronically at the following Internet site: *https://intranet.epa.gov/lt2/*. These PWSs should instruct their laboratories to electronically enter results at this site using web-based manual entry forms or by uploading XML files (extensible markup language files—a standard format that enables information exchange between different systems) from laboratory information management systems (LIMS). After laboratories enter sample results, PWSs must review the results on-line at this site. The State may approve an alternative approach for reporting source water monitoring schedules and sample results if, for example, a PWS or laboratory does not have the capability to report data electronically.

If a PWS believes that its laboratory entered a sample result into the data system erroneously, the PWS may notify the laboratory to rectify the entry. In addition, if a PWS believes that a result is incorrect, the PWS may electronically mark the result as contested and petition the State to invalidate the sample. If a PWS contests a sample result, the PWS should submit a rationale to the State, including a supporting statement from the laboratory, providing a justification. PWSs may arrange with laboratories to review their sample results prior to the results being entered into the EPA data system.

PWSs serving fewer than 10,000 people must submit sampling schedules and monitoring results for the initial round of source water monitoring to the State. Further, all PWSs must submit sampling schedules and monitoring results for the second round of

monitoring to the State. Regardless of the reporting process used, PWSs must report an analytical monitoring result to the State no later than 10 days after the end of the first month following the month when the sample was collected.

2. Background and Analysis

The reporting requirements for source water monitoring in today's final rule reflect those in the August 11, 2003 proposed LT2ESWTR (USEPA 2003a). The data elements that PWSs must report for Cryptosporidium and E. coli analyses are the minimum necessary to identify the sample, determine the sample concentration, and verify that the PWS complied with rule requirements like minimum sample volume and approved analytical methods. PWSs or laboratories must keep bench sheets and slide reports for Cryptosporidium analyses for three years after bin determination for the particular round of monitoring, at which time PWSs must be in compliance with any additional Cryptosporidium treatment requirements based on the monitoring results.

Due to the early implementation schedule, EPA expects to partner with States to implement initial source water monitoring by large PWSs under today's rule. EPA has developed an Internet-based data system to allow electronic reporting and review of source water monitoring results by laboratories, PWSs, States, and EPA. States may use this data system to oversee monitoring by their PWSs. Where States are unable to provide this oversight, the data system will allow EPA to implement today's rule. Accordingly, PWSs serving at least 10,000 people must use this data system to report sampling schedules and sample results for the initial round of source water monitoring unless the State approves an alternative method for reporting.

EPA expects laboratories to report analytical results for Cryptosporidium, E. coli, and turbidity analyses directly to the data system using web forms and software that are available free of charge. The data system will perform logic checks on data entered and will calculate results from primary data where necessary. This is intended to reduce reporting errors and limit the time involved in investigating, checking, and correcting errors at all levels. The LT2ESWTR proposal describes the analysis functions of the data system in more detail (USEPA 2003a).

In general, EPA expects that States will implement the initial source water monitoring by small PWSs and the second round of monitoring by all PWSs. Thus, PWSs must submit sampling schedules and monitoring results for this monitoring to the State. Note that where States do not assume primacy for the rule, however, EPA will act as the State.

3. Summary of Major Comments

EPA received significant public comment on the following aspects of reporting requirements for source water monitoring in the August 11, 2003 proposed LT2ESWTR: the deadline for reporting sample results, EPA's electronic data system, and reporting results to EPA rather than the State. A summary of these comments and EPA's responses follows.

Some commenters were concerned with requiring PWSs to report sample results no later than the 10th of the second month after the month when the sample is collected. Commenters stated that this will cause most PWSs to sample in the first part of the month, which will exacerbate laboratory capacity problems. As an alternative, commenters recommended that PWSs be required to report sample results 72 days after collection. This approach would give all PWSs the same time period to report sample results regardless of the collection date and would facilitate PWSs and laboratories scheduling sample collection dates more uniformly throughout the month.

In response, EPA believes that requiring PWSs to report monitoring results by the 10th of the second month after sample collection is appropriate. This will maintain consistency with existing drinking water regulations, which typically require monitoring results to be reported by the 10th of the following month. Thus, specifying this reporting date under today's rule will avoid causing PWSs and States to develop different reporting dates for different regulations. Due to the time required for laboratories to analyze Cryptosporidium samples, today's rule gives PWSs an extra month to report monitoring results; i.e., the minimum time PWSs have to report results is approximately 40 days (one month plus 10 days). This time frame, however, is greater than what is necessary for laboratories to analyze samples and for PWSs to review results. Consequently, EPA does not believe that PWSs will benefit by collecting a sample at the start of a month in comparison to the end of a month.

Many commenters expressed concern with the readiness of the electronic data system for reporting and reviewing monitoring results under today's rule. Commenters stated that PWSs have experienced significant problems with data systems that supported earlier rules, such as the Information Collection Rule and the Unregulated Contaminant Monitoring Rule. Commenters recommended that the data system be in place and fully tested prior to finalization of the rule and that EPA provide training for users. If the data system is not available when the rule is finalized, commenters asked that the monitoring be delayed as specified in the Agreement in Principle (USEPA 2000a).

EPA has ensured that the LT2 data system has been fully tested and deployed prior to finalizing the rule. During development of the data system, EPA has involved stakeholders in a joint requirements workgroup, which has made recommendations for data system characteristics and has participated in data system testing. EPA has developed guidance and other training materials for PWSs, States, and laboratories on how to use the data system and will provide technical assistance on a ongoing basis to data system users. EPA believes these steps will help to avoid problems that stakeholders experienced with data systems for earlier rules.

Some commenters expressed concerns about large PWSs reporting monitoring results to EPA. Commenters stated that implementation of the rule should be administered by States, due to the existing relationships States have with the PWSs they regulate. For States that will implement the rule, commenters recommended allowing PWSs to report to States, rather than EPA. Commenters also requested that EPA provide copies of all monitoring data and PWS correspondence to States when they assume primacy.

EPA will work with States to implement today's rule and to help States assume as much responsibility for implementation as they can. Through the LT2ESWTR data system, States will have full access to monitoring results reported by their PWSs. Today's rule also allows States to direct their PWSs to report monitoring results directly to them, rather than EPA. Further, States may require PWSs to submit descriptions of monitoring locations for approval. In general, EPA will seek to involve States in any communications with and decisions for their PWSs and will allow States to take responsibility for these activities if they choose to do so. However, because monitoring for the largest systems begins before States will have had time to assume primacy, EPA must be prepared to oversee monitoring for these PWSs where States are unable to do so.

J. Analytical Methods

1. Analytical Methods Overview

Today's final rule requires public water systems to conduct LT2ESWTR source water monitoring using approved methods for Cryptosporidium, E. coli, and turbidity analyses. PWSs must meet the quality control criteria stipulated by the approved methods and additional method-specific requirements, as stated in this section. Related requirements for reporting source water monitoring results and using approved laboratories are discussed in sections IV.I and IV.K, respectively.

EPA has developed guidance for sampling and analyses under the LT2ESWTR. The Source Water Monitoring Guidance Manual for Public Water Systems under the LT2ESWTR provides recommendations on activities like collecting samples and setting up contracts with laboratories. The Microbial Laboratory Manual for the LT2ESWTR provides information for laboratories that conduct analyses. These guidance documents may be requested from EPA's Safe Drinking Water Hotline, which may be contacted as described in the **FOR FURTHER INFORMATION CONTACT** section in the beginning of this notice, and are available on the Internet at *www.epa.gov/safewater/disinfection/lt2.*

2. Cryptosporidium Methods

a. Today's Rule

Cryptosporidium analysis for source water monitoring under today's rule must be conducted using either Method 1622: Cryptosporidium in Water by Filtration/IMS/FA (EPA 815–R–05–001, USEPA 2005c) or Method 1623: Cryptosporidium and Giardia in Water by Filtration/IMS/FA (EPA 815–R–05–002, USEPA 2005d). Additional method requirements for today's rule include the following:

- For each Cryptosporidium sample, at least a 10–L sample volume must be analyzed unless a PWS meets one of the two exceptions stated in this section. PWSs may collect and analyze greater than a 10–L sample volume.
- The first exception to the sample volume requirement stems from sample turbidity. If a sample is very turbid, it may generate a large packed pellet volume upon centrifugation (a packed pellet refers to the concentrated sample after centrifugation has been performed in EPA Methods 1622 and 1623). Samples resulting in large packed pellets must have the sample concentrate aliquoted into multiple ''subsamples'' for independent processing through IMS, staining, and examination. PWSs are not required to analyze more than 2 mL of packed pellet volume per sample.
- The second exception to the sample volume requirement stems from filter clogging. In cases where the filter clogs prior to filtration of 10 L, the PWS must analyze as much sample volume as can be filtered by 2 filters, up to a packed pellet volume of 2 mL. This condition applies only to filters that have been approved by EPA for nationwide use with Methods 1622 and 1623—the Pall Gelman Envirochek™ and Envirochek™ HV filters, the IDEXX Filta-Max™ foam filter, and the Whatman CrypTest™ cartridge filter.
- Methods 1622 and 1623 include fluorescein isothiocyanate (FITC) as the primary antibody stain for Cryptosporidium detection, DAPI staining to detect nuclei, and DIC to detect internal structures. Under today's rule, PWSs must report total Cryptosporidium oocysts as detected by FITC as determined by the color (apple green or alternative stain color approved for the laboratory under the Lab QA Program described in section IV.K), size (4–6 micrometers) and shape (round to oval). This total includes all of the oocysts identified as described here, less any atypical organisms identified by FITC, DIC, or DAPI (e.g., possessing spikes, stalks, appendages, pores, one or two large nuclei filling the cell, red fluorescing chloroplasts, crystals, spores, etc.).
- As required by Method 1622 and 1623, PWSs must have 1 matrix spike (MS) sample analyzed for each 20 source water samples. The volume of the MS sample must be within ten percent of the volume of the unspiked sample that is collected at the same time, and the samples must be collected by splitting the sample stream or collecting the samples sequentially. The MS sample and the associated unspiked sample must be analyzed by the same procedure. MS samples must be spiked and filtered in the laboratory. However, if the volume of the MS sample is greater than 10 L, the PWS is permitted to filter all but 10 L of the MS sample in the field, and ship the filtered sample and the remaining 10 L of source water to the laboratory. In this case, the laboratory must spike the remaining 10 L of water and filter it through the filter that was used to collect the balance of the sample in the field.
- Laboratories must use flow cytometer-counted spiking suspensions for spiked QC samples.

b. Background and Analysis

The M–DBP Advisory Committee recommended the use of Methods 1622 or 1623 and a minimum sample volume of 10 L for source water Cryptosporidium analyses under the LT2ESWTR. The August 11, 2003 proposed rule reflected these recommendations, with associated QC requirements and exceptions to the minimum sample volume for samples that are highly turbid or cause significant filter clogging (USEPA 2003a). Today's final rule is unchanged from the proposal in these respects.

Today's rule requires the use of methods 1622 or 1623 because they are the best available methods that have undergone full validation testing. As described in section III.E, these methods were used during the ICRSS, where MS samples indicated a mean recovery and relative standard deviation of 43 and 47 percent, respectively (Connell et al. 2000). EPA expects that PWSs will achieve comparable performance with these methods during source water monitoring under today's rule. With the minimum sample volume and QC requirements in today's rule, this level of performance will be sufficient to assign PWSs to Cryptosporidium treatment bins and realize the public health goals intended by EPA and the Advisory Committee for the LT2ESWTR. EPA has also approved these methods for ambient water monitoring under a separate rulemaking (68 FR 43272, July 21, 2003) (USEPA 2003b).

The proposed LT2ESWTR required the use of April 2001 versions of Methods 1622 or 1623 and requested comment on approving revised versions of these methods in the final rule (USEPA 2003a). The revised methods were included in the proposal as draft June 2003 versions. The revisions in these versions included increased flexibility in some QC requirements, clarification of certain method procedures, an increase in the allowable sample storage temperature to 10°C, the addition of several approved analysis modifications, and other refinements (see the proposed rule for details)(USEPA 2003a).

Today's rule requires the use of the revised versions of Methods 1622 and 1623. In the versions of these methods finalized with today's rule, the upper temperature limit for sample receipt has been increased to 20°C. This change responds to public comment and recent publications (Ware and Schafer 2005, Francy et al. 2004, Nichols et al. 2004). As described in section IV.A, PWSs may grandfather data generated with earlier approved versions of these methods (i.e., 1999 or 2001 versions).

c. Summary of Major Comments

Public comment on the August 11, 2003 proposed LT2ESWTR supported approval of the revised versions of Methods 1622 and 1623, which today's rule establishes for source water Cryptosporidium monitoring. EPA also received comment regarding the lack of viability and infectivity information with these methods and requirements for analyzing QC samples.

Several commenters were concerned that Methods 1622 and 1623 do not indicate whether a Cryptosporidium oocyst is viable and infectious. While EPA recognizes that these methods do not provide information on Cryptosporidium infectivity, EPA's analysis indicates that they can perform effectively for identifying those PWSs that should provide additional Cryptosporidium treatment (USEPA 2005a). This analysis is based on the actual performance of these methods in the ICRSS. Further, EPA and the M–DBP Advisory Committee, which recommended Methods 1622 and 1623, accounted for this lack of information on infectivity when designing the Cryptosporidium treatment bins in today's rule. EPA has not identified any feasible methods for quantifying Cryptosporidium infectivity in a national monitoring program.

Several commenters suggested that laboratories should only be required to perform one OPR test per day instead of one for every 20 samples, as Methods 1622 and 1623 require. EPA believes, however, that the frequency of one OPR test per 20 samples is appropriate for identifying and correcting problems. For example, if an OPR test is performed once per day for a laboratory that processes 60 samples per day, a problem that occurs at sample 10 will be continued through the next 50 samples. If an OPR test is performed once per 20 samples, a problem that occurs at sample 10 would only affect 10 additional samples. Consequently, EPA is maintaining the current QC criteria in Methods 1622 and 1623.

3. E. coli Methods

a. Today's Rule

For enumerating source water E. coli density under the LT2ESWTR, EPA is approving the same methods that are currently approved for ambient water monitoring under 40 CFR 136.3. EPA established these methods through the rulemaking ''Guidelines Establishing Test Procedures for the Analysis of Pollutants; Analytical Methods for Biological Pollutants in Ambient Water'' (USEPA 2003b). Table IV.J–1 summarizes these methods. Method identification numbers are provided for applicable standards published by EPA and voluntary consensus standards bodies including Standard Methods, American Society of Testing Materials (ASTM), and the Association of Analytical Chemists (AOAC).

TABLE IV.J–1.—LIST OF APPROVED ANALYTICAL METHODS FOR E. COLI [1]

Method	EPA	Standard Methods 18th, 19th, 20th Ed.	ASTM	AOAC	Other
MPN [2 3 4], multiple tube		9221B.1/9221F [5 6 7].			
Multiple tube/multiple well		9223B [5 8]		991.15 [9]	Colilert® [8 10], Colilert-18® [8 10 11].
MF [2 3 12 13 14] two step, or	1103.1 [16]	9222B/9222G [5 15] 9213D [5]	D5392–93 [17].		
Single step	1603 [18], 1604 [19].				mColiBlue 24 [20].

[1] Recommended for enumeration of E. coli in ambient water only, number per 100 ml.

[2] Tests must be conducted to provide organism enumeration (density). Select the appropriate configuration of tubes/filtrations and dilutions/volumes to account for the quality, character, consistency, and anticipated organism density of the water sample.

[3] To assess the comparability of results obtained with individual methods, it is suggested that side-by-side tests be conducted across seasons of the year with the water samples routinely tested in accordance with the most current Standard Methods for the Examination of Water and Wastewater or EPA alternate test procedure (ATP) guidelines.

[4] Samples shall be enumerated by the multiple-tube or multiple-well procedure. Using multiple-tube procedures, employ an appropriate tube and dilution configuration of the sample as needed and report the Most Probable Number (MPN). Samples tested with Colilert® may be enumerated with the multiple-well procedures, Quanti-tray®, or Quanti-tray® 2000, and the MPN calculated from the table provided by the manufacturer.

[5] APHA. 1998, 1995, 1992. Standard Methods for the Examination of Water and Wastewater. American Public Health Association. 20th, 19th, and 18th Editions. Amer. Publ. Hlth. Assoc., Washington, DC.

[6] The multiple-tube fermentation test is used in 9221.B.1. Lactose broth may be used in lieu of lauryl tryptose broth (LTB), if at least 25 parallel tests are conducted between this broth and LTB using the water samples normally tested, and this comparison demonstrates that the false-positive rate and false-negative rate for total coliform using lactose broth is less than 10 percent. No requirement exists to run the completed phase on 10 percent of all total coliform-positive tubes on a seasonal basis.

[7] After prior enrichment in a presumptive medium for total coliform using 9221B.1, all presumptive tubes or bottles showing any amount of gas, growth or acidity within 48± 3 h of incubation shall be submitted to 9221F. Commercially available EC–MUG media or EC media supplemented in the laboratory with 50 μg/ml of MUG may be used.

[8] These tests are collectively known as defined enzyme substrate tests, where, for example, a substrate is used to detect the enzyme glucuronidase produced by E. coli.

[9] AOAC. 1995. Official Methods of Analysis of AOAC International, 16th Edition, Volume 1, Chapter 17. Association of Official Analytical Chemists International. 481 North Frederick Avenue, Suite 500, Gaithersburg, Maryland 20877–2417.

[10] Descriptions of the Colilert®, Colilert-18®, Quanti-Tray® and Quanti-Tray® 2000 may be obtained from IDEXX Laboratories, Inc., One IDEXX Drive, Westbrook, Maine 04092.

[11] Colilert-18® is an optimized formulation of the Colilert® for the determination of total coliforms and E. coli that provides results within 18 h of incubation at 35 °C rather than the 24 h required for the Colilert® test and is recommended for marine samples.

[12] A 0.45 μm membrane filter (MF) or other pore size certified by the manufacturer to fully retain organisms to be cultivated and to be free of extractables which could interfere with their growth.

[13] Because the MF technique usually yields low and variable recovery from chlorinated wastewaters, the Most Probable Number method will be required to resolve any controversies.

[14] When the MF method has not been used previously to test ambient water with high turbidity, large number of noncoliform bacteria, or samples that may contain organisms stressed by chlorine, a parallel test should be conducted with a multiple-tube technique to demonstrate applicability and comparability of results.

[15] Subject total coliform positive samples as determined by 9222B or other membrane filter procedure to 9222G using NA–MUG media.

[16] USEPA. 2002c. Method 1103.1: Escherichia coli (E. coli) In Water By Membrane Filtration Using membrane-Thermotolerant Escherichia coli Agar (mTEC). U.S. Environmental Protection Agency, Office of Water, Washington, DC. EPA–821–R–02–020.

[17] ASTM. 2000, 1999, 1996. Annual Book of ASTM Standards—Water and Environmental Technology. Section 11.02. American Society for Testing and Materials. 100 Barr Harbor Drive, West Conshohocken, PA 19428.

[18] USEPA. 2002. Method 1610: Escherichia coli (E. coli) In Water By Membrane Filtration Using Modified membrane-Thermotolerant Escherichia coli Agar (modified mTEC). U.S. Environmental Protection Agency, Office of Water, Washington, DC. EPA–821–R–02–023.

[19] Preparation and use of MI agar with a standard membrane filter procedure is set forth in the article, Brenner et al. 1993. ''New Medium for the Simultaneous Detection of Total Coliform and Escherichia coli in Water.'' Appl. Environ. Microbiol. 59:3534–3544 and in USEPA. 2002. Method 1604: Total Coliforms and Escherichia coli (E. coli) in Water by Membrane Filtration by Using a Simultaneous Detection Technique (MI Medium). U.S. Environmental Protection Agency, Office of Water, Washington, DC. EPA–821–R–02–024.

[20] A description of the mColiBlue24 test, Total Coliforms and E. coli, is available from Hach Company, 100 Dayton Ave., Ames, IA 50010.

For most PWSs, the time from sample collection to initiation of analysis (i.e., the holding time) for source water E. coli samples may not exceed 30 hours for all approved E. coli methods. However, if the State determines on a case-by-case basis that analyzing an E. coli sample within 30 hours is not feasible, the State may approve the holding of an E. coli sample for up to 48 hours between collection and initiation of analysis. E. coli samples held between 30 to 48 hours must be analyzed by the Colilert reagent version of Standard Method 9223B as listed in 40 CFR 136.3. All E. coli samples must be maintained below 10° C and not allowed to freeze.

The E. coli sample holding time established for source water monitoring under the LT2ESWTR does not apply to E. coli sample holding time requirements that have been established under other programs and regulations.

b. Background and Analysis

In the August 11, 2003 proposed LT2ESWTR, EPA planned to approve the same E. coli methods that the Agency had proposed for ambient water monitoring in an earlier rulemaking, ''Guidelines Establishing Test Procedures for the Analysis of Pollutants; Analytical Methods for Biological Pollutants in Ambient Water'' (USEPA 2001h). EPA selected these methods based on data generated by EPA laboratories, submissions to the EPA alternate test procedures program and voluntary consensus standards bodies, peer reviewed journal articles, and publicly available study reports.

On July 21, 2003, EPA finalized ''Guidelines Establishing Test Procedures for the Analysis of Pollutants; Analytical Methods for Biological Pollutants in Ambient Water'' (USEPA 2003b). The only method from the proposal of this rule that was not included in the final rule was Colisure, which was excluded due to insufficient data on its performance with surface water. For the other methods, EPA revised certain titles and added method numbers to be consistent with other microbiological methods, but the technical content of these methods in the final rule did not change from the versions included in the proposed rule.

EPA is approving these same E. coli methods for analyses under the LT2ESWTR. The source water E. coli analyses that PWSs will conduct under the LT2ESWTR are similar to the ambient water analyses for which EPA approved E. coli methods under ''Guidelines Establishing Test Procedures for the Analysis of Pollutants; Analytical Methods for Biological Pollutants in Ambient Water'' (USEPA 2003b). EPA continues to support the findings of this rule and believes that the E. coli methods approved therein have the necessary sensitivity and specificity to meet the data quality objectives of the LT2ESWTR.

An important aspect of monitoring for E. coli is the allowable sample holding time (i.e., the time between sample collection and initiation of analysis). Existing regulations, such as 40 CFR 141.74, limit the holding time for E. coli samples to 8 hours. However, for PWSs that must ship E. coli samples to an off-site laboratory for analysis, meeting an 8 hour holding time is generally not feasible. For example, during the ICRSS, all of the PWSs that shipped samples off-site for E. coli analysis exceeded an 8 hour holding time, and 12 percent of these samples had holding times in excess of 30 hours.

While most large PWSs that will monitor for E. coli under the LT2ESWTR will conduct these analyses on-site, most small PWSs must ship samples off-site to an approved laboratory. To address the concern that PWSs using off-site laboratories cannot meet an 8-hour holding time, EPA participated in studies to assess the effect of increased sample holding time on E. coli analysis results. These studies are summarized in the proposed rule (USEPA 2003a) and are described in detail in Pope et al. (2003). Based on these studies, EPA has concluded that the holding time for E. coli samples can be extended beyond 8 hours prior to analysis without compromising the data quality objectives of LT2ESWTR monitoring.

In the proposed LT2ESWTR, EPA required analysis of E. coli samples to be initiated within 24 hours of sample collection and required that samples be kept below 10° C and not allowed to freeze (USEPA 2003a). These proposed requirements were based on data showing that most samples maintained within these temperature conditions were not significantly different at 24 hours than at the standard holding time of 8 hours. The proposal also noted that data indicated no significant sample degradation after longer time periods, such as 30 or 48 hours, for certain methods. Accordingly, EPA requested comment on establishing a longer E. coli holding time in the final rule.

For today's final rule, EPA is establishing a holding time of 30 hours for all approved E. coli methods. After reviewing public comment on this issue, which is summarized in the following section, and reassessing the studies described in the proposed rule, EPA has concluded that a 30 hour holding time limit for E. coli samples is appropriate and consistent with the data quality objectives of LT2ESWTR source water monitoring. Further, EPA believes that meeting a 30 hour holding time is feasible for most PWSs that must ship E. coli samples to an off-site laboratory for analysis. This longer holding time, however, does not apply to E. coli monitoring conducted under other programs and regulations.

EPA recognizes that in rare cases, having an E. coli sample analyzed within 30 hours may not be feasible for a PWS due to distance to an approved laboratory and limited transportation options. In these cases, today's rule allows the State to approve up to a 48 hour holding time for E. coli samples. Samples held between 30 to 48 hours must be analyzed by the Colilert reagent version of Standard Method 9223B. This is the only method evaluated in Pope et al. (2003) where no significant sample degradation occurred at 48 hours.

PWSs must maintain samples below 10°C and not allow them to freeze. EPA has developing guidance for PWSs on packing and shipping E. coli samples to maintain these temperature conditions. See the overview at the beginning of this section for information on how to access this guidance.

c. Summary of Major Comments

In the August 11, 2003 LT2ESWTR proposal, EPA requested comment on whether the E. coli methods proposed for approval under the LT2ESWTR are appropriate and whether there are additional methods not proposed that should be considered. EPA also requested comment on the proposal to extend the holding time for E. coli

samples to 24 hours; whether EPA should limit the extended holding time to only those E. coli analytical methods that were evaluated in the holding time studies described in the proposal; and whether EPA should increase the source water E. coli holding time to 30 or 48 hours for samples evaluated by one method, ONPG–MUG, and retain a 24-hour holding time for samples analyzed by other methods.

Most commenters stated that the proposed E. coli analytical methods are appropriate. Commenters also agreed with the proposal to extend the holding time for source water E. coli samples, but recommendations about the maximum holding time and the methods to which the extended holding time should apply differed among commenters. Some suggested that EPA increase the holding time to 30 hours for the ONPG–MUG method, but retain a 24-hour holding time for the other methods. Other commenters recommended a 48-hour holding time for some or all methods. Several commenters advised that holding times for all methods should be the same to limit confusion. Some commenters were concerned that a 30-hour holding time would not be sufficient for small PWSs in remote areas to ship samples to distant laboratories.

After consideration of the comments received, as well as the holding time study data presented in the proposed rule and the time required to ship samples off-site for analysis as evidenced in the ICRSS, EPA has concluded that allowing a 30-hour holding time for all E. coli methods approved under today's final rule is appropriate. Data indicate that a 30-hour holding time for E. coli samples will not adversely impact the data quality objectives of LT2ESWTR monitoring. Further, establishing the same holding time for all methods will limit confusion, and a 30-hour holding time will allow most PWSs that ship samples off site for analysis to meet the holding time requirements. Today's rule also allows the State to authorize a 48-hour holding time for rare cases where a 30-hour holding time is not feasible.

4. Turbidity Methods

a. Today's Rule

Today's rule requires PWSs to use the analytical methods that have been previously approved by EPA for analysis of turbidity in drinking water, as listed in 40 CFR 141.74. These are Method 2130B as published in Standard Methods for the Examination of Water and Wastewater (APHA 1992), EPA Method 180.1 (USEPA 1993), Great Lakes Instruments Method 2 (Great Lakes Instruments 1992), and Hach FilterTrak Method 10133.

b. Background and Analysis

As stated in section IV.A, today's rule requires filtered PWSs serving at least 10,000 people to monitor for turbidity when they conduct source water monitoring. EPA may use these data to modify the indicator criteria that trigger Cryptosporidium monitoring by small filtered PWSs, as recommended by the M–DBP Advisory Committee (USEPA 2000a). In addition, PWSs using conventional or direct filtration may achieve additional Cryptosporidium treatment credit by demonstrating very low turbidity in the combined filter effluent, as described in section IV.D.7, or the individual filter effluent, as described in section IV.D.8.

The August 11, 2003 proposed LT2ESWTR required PWSs to use turbidity methods that EPA had previously approved under 40 CFR 141.74 for analyzing drinking water (USEPA 2003a). These are EPA Method 180.1 and Standard Method 2130B, which are based on a comparison of the intensity of light scattered by the sample with the intensity of light scattered by a standard reference suspension; Great Lakes Instruments Method 2, which is a modulated four beam infrared method using a ratiometric algorithm to calculate the turbidity value from the four readings that are produced; and Hach FilterTrak (Method 10133), which is a laser-based method used to analyze finished drinking water.

Today's final rule is unchanged from the proposal in regard to analytical methods for turbidity. Hence, PWSs must use methods currently approved in 40 CFR 141.74 for turbidity analysis. EPA believes the currently approved methods are appropriate for turbidity analyses that will be conducted under the LT2ESWTR. PWSs must use turbidimeter instruments as described in the EPA-approved methods, which may be either on-line or bench top instruments. If a PWS chooses to use on-line instruments for monitoring turbidity, the PWS must validate the continuous measurements for accuracy on a regular basis using a protocol approved by the State, as required in 40 CFR 141.74.

c. Summary of Major Comments

EPA received public comment on the turbidity methods required in the August 11, 2003 proposed LT2ESWTR. While commenters, in general, agreed that currently approved turbidity methods are adequate to meet the requirements of the rule, several commenters were concerned with turbidity measurement variation among different instruments. One commenter suggested voluntary third party testing, while another recommended more rigorous calibration and verification processes.

As described in section IV.D.7, EPA has reviewed studies of low level turbidity measurements, as well as standard test methods for measurement of turbidity below 5 NTU. After reviewing this information, EPA concluded that currently available monitoring equipment can reliably measure turbidity at levels of 0.15 NTU and lower. However, EPA agrees that rigorous calibration and maintenance of turbidity monitoring equipment is necessary for PWSs pursuing the low filtered water turbidity performance options in the microbial toolbox. EPA has developed guidance on proper calibration, operation, and maintenance of turbidimeters (USEPA 1999c).

A few commenters stated that the LT2ESTWR does not recognize advancements in turbidity measurement and newly developed turbidity measurement technologies. In response, EPA has not received information that supports approval of analytical methods for turbidity in addition to those currently approved under 40 CFR 141.74, which are also approved for turbidity monitoring under today's rule. If other turbidity methods are approved and added to 40 CFR 141.74 in the future, these methods will also be approved under the LT2ESWTR.

One commenter requested that the LT2ESWTR specifically address turbidity measurements in plants that practice lime softening. EPA notes that additional treatment credit for combined filter effluent turbidity is based on measurements collected under 40 CFR 141.173 or 40 CFR 141.551 (the IESWTR or LT1ESWTR). These regulations allow PWSs that use lime softening to acidify samples prior to analysis in order to address the effects of lime softening on turbidity measurements. In regard to treatment credit based on individual filter effluent turbidity, EPA does not believe that acidifying samples while measuring turbidity every 15 minutes at each individual filter, as the IESWTR and LT1ESWTR require, is feasible. However, PWSs that practice lime softening could use the demonstration of performance toolbox option to demonstrate that a plant is achieving removal efficiencies equivalent to the additional credit allowed for individual filter performance.

K. Laboratory Approval

Given the potentially significant implications for PWSs and drinking water consumers of microbial monitoring under the LT2ESWTR, laboratory analyses for Cryptosporidium, E. coli, and turbidity should be accurate and reliable within the limits of approved methods. Therefore, today's final rule requires PWSs to use laboratories that have been approved to conduct analyses for these parameters by EPA or the State.

1. Cryptosporidium Laboratory Approval

a. Today's Rule

Analysis of samples for Cryptosporidium under today's rule must be conducted by a laboratory that is approved under EPA's Laboratory Quality Assurance Evaluation Program (Lab QA Program) for Analysis of Cryptosporidium in Water (described in 67 FR 9731, March 4, 2002, USEPA 2002d). A list of laboratories that are approved under this program is available on the Internet at *www.epa.gov/safewater/disinfection/lt2*. If a State adopts an equivalent approval process under a State laboratory certification program, then PWSs can use laboratories approved by the State.

b. Background and Analysis

Because States do not currently approve laboratories for Cryptosporidium analyses, EPA has assumed initial responsibility for Cryptosporidium laboratory approval. EPA initiated the Cryptosporidium Lab QA Program prior to LT2ESWTR promulgation to ensure that adequate analytical capacity will be available at approved laboratories to support required monitoring, which begins 6 months after rule promulgation. The August 11, 2003 proposed LT2ESWTR required PWSs to have Cryptosporidium samples analyzed by laboratories approved under the EPA Lab QA Program. Today's final rule is unchanged from the proposal with respect to this requirement.

Laboratories seeking approval under the EPA Lab QA Program for Cryptosporidium analysis must submit an interest application to EPA, successfully analyze a set of initial performance testing samples, and undergo an on-site evaluation. Laboratories that pass the quality assurance evaluation are approved for Cryptosporidium analysis under the LT2ESWTR. To maintain approval, laboratories must successfully analyze a set of three ongoing proficiency testing samples approximately every four months. The Lab QA Program is described in detail in USEPA (2002d) and additional information can be found on the Internet at *www.epa.gov/safewater/disinfection/lt2*.

EPA tracks the Cryptosporidium sample analysis capacity of approved laboratories through the Lab QA Program. Using information provided by laboratories, EPA expects that existing capacity should be sufficient to support initial source water monitoring by large PWSs under the LT2ESWTR. Further, the implementation schedule for today's rule, which is described in section IV.G, provides time for laboratories to increase capacity through steps like training new analysts as the demand for sample analysis grows.

c. Summary of Major Comments

In regard to approval of laboratories for Cryptosporidium analysis, major comments on the August 11, 2003 proposal addressed the following issues: laboratory capacity, State approval programs, and analyst experience criteria. Comments regarding Cryptosporidium laboratory capacity are summarized in section IV.G, while those on the other issues are summarized as follows.

EPA requested comment on States approving Cryptosporidium laboratories. Most commenters, however, recommended that EPA maintain the Lab QA Program, due to the specialized nature of the work. EPA intends to maintain the Lab QA Program, but today's rule does allow States to certify Cryptosporidium laboratories by setting up an equivalent program.

EPA also requested comment on the experience criteria that Methods 1622 and 1623 include for Cryptosporidium analysts. Some commenters recommended lowering analyst training and experience requirements, while others recommended no change or an increase in microscopy training. After evaluating these comments, EPA has concluded that the analyst criteria included in Methods 1622 and 1623 are reasonable for ensuring that analysts have the experience to evaluate source water samples under today's rule. Consequently, EPA has not altered these criteria from the approved methods.

2. E. coli Laboratory Approval

a. Today's Rule

PWSs must have E. coli samples analyzed by a laboratory that has been certified by EPA, the National Environmental Laboratory Accreditation Conference (NELAC) or the State for total coliform or fecal coliform analysis in drinking water under 40 CFR 141.74. The laboratory must use the same technique for E. coli analysis under today's rule that the laboratory is certified to use for drinking water under 40 CFR 141.74 (e.g., membrane filtration, multiple-well, multiple-tube).

b. Background and Analysis

The August 11, 2003 proposed LT2ESWTR required PWSs to have E. coli samples analyzed by laboratories that are certified to conduct total or fecal coliform analyses in drinking water (i.e., under 40 CFR 141.74) by EPA, NELAC or the State. The proposal required laboratories to use the same E. coli analytical technique that they are certified to use for coliform analyses in drinking water. Today's final rule is unchanged from the proposal in regard to these requirements. EPA believes that laboratories that are certified to conduct coliform analyses in drinking water have the expertise to conduct E. coli analyses under today's rule, provided they use the analytical technique for which they are certified.

c. Summary of Major Comments

Two commenters on the August 11, 2003 proposal suggested that laboratories should be certified specifically for quantitative analyses of total or fecal coliform in a source water matrix. However, the methods approved for source water E. coli analyses under today's rule are also approved under the drinking water certification program. EPA believes that analysts certified for these methods under the drinking water certification program have the capability to perform the same methods for a source water matrix, even though additional steps may be required (such as dilutions). EPA has revised the Laboratory Certification Manual to suggest Performance Evaluation (PE) samples for source water matrix analyses and States have the option to require PE samples as needed in their State laboratory certification programs.

3. Turbidity Analyst Approval

a. Today's Rule

Under today's rule, measurements of turbidity must be made by a party approved by the State.

b. Background and Analysis

The August 11, 2003 proposed LT2ESWTR required that measurements of turbidity be made by a party approved by the State. This reflects existing requirements in 40 CFR 141.74 for measurement of turbidity in drinking water. Today's final rule is unchanged from the proposal in this respect.

c. Summary of Major Comments

Commenters on requirements for turbidity analyst approval in the August 11, 2003 proposal agreed that turbidity analyses should be consistent with 40 CFR 141.74. Specifically, any person that is currently approved to conduct turbidity analysis under existing drinking water regulations should be approved to conduct turbidity analyses under the LT2ESWTR. EPA agrees with this comment and it is reflected in today's final rule.

L. Requirements for Sanitary Surveys Conducted by EPA

1. Today's Rule

Today's final rule establishes requirements for PWSs to respond to significant deficiencies identified in sanitary surveys that EPA conducts. These requirements give EPA authority equivalent to that exercised by States under existing regulations to ensure that PWSs address significant deficiencies.

- For sanitary surveys conducted by EPA under SDWA section 1445 or other authority, PWSs must respond in writing to significant deficiencies outlined in sanitary survey reports no later than 45 days after receipt of the report, indicating how and on what schedule the PWS will address significant deficiencies noted in the survey.
- PWSs must correct significant deficiencies identified in sanitary survey reports according to the schedule approved by EPA, or if there is no approved schedule, according to the schedule the PWS reported if such deficiencies are within the control of the PWS.
- A sanitary survey, as conducted by EPA, is an onsite review of the water source (identifying sources of contamination by using results of source water assessments where available), facilities, equipment, operation, maintenance, and monitoring compliance of a PWS to evaluate the adequacy of the PWS, its sources and operations, and the distribution of safe drinking water. A significant deficiency includes a defect in design, operation, or maintenance, or a failure or malfunction of the sources, treatment, storage, or distribution system that EPA determines to be causing, or has the potential for causing the introduction of contamination into the water delivered to consumers.

2. Background and Analysis

As established by the IESWTR in 40 CFR 142.16(b)(3), primacy States must conduct sanitary surveys for PWSs using surface water sources every three or five years. The sanitary survey is an onsite review of the following: (1) Source, (2) treatment, (3) distribution system, (4) finished water storage, (5) pumps, pump facilities, and controls, (6) monitoring, reporting, and data verification, (7) system management and operation, and (8) operator compliance with State requirements.

Under the IESWTR, primacy States must have the authority to assure that PWSs respond in writing to significant deficiencies identified in sanitary survey reports no later than 45 days after receipt of the report, indicating how and on what schedule the system will address the deficiency (40 CFR 142.16(b)(1)(ii)). Further, primacy States must have the authority to assure that systems take necessary steps to address significant deficiencies identified in sanitary survey reports if such deficiencies are within the control of the system and its governing body (40 CFR 142.16(b)(1)(iii)).

EPA conducts sanitary surveys under SDWA section 1445 for PWSs not regulated by primacy States (e.g., Tribal systems, Wyoming). However, the authority required of primacy States under 40 CFR 142 to ensure that PWSs address significant deficiencies identified during sanitary surveys does not extend to EPA. Consequently, the sanitary survey requirements established by the IESWTR created an unequal standard. PWSs regulated by primacy States are subject to the States' authority to require correction of significant deficiencies noted in sanitary survey reports, while PWSs for which EPA has direct implementation authority did not have to meet an equivalent requirement.

In the August 11, 2003 proposal, EPA requested comment on establishing requirements under 40 CFR 141 for PWSs to correct significant deficiencies identified in sanitary surveys conducted by EPA. The requirements in today's final rule follow closely on the language presented in the proposal. Today's rule ensures that PWSs in non-primacy States are subject to comparable requirements for sanitary surveys as PWS regulated by States with primacy.

3. Summary of Major Comments

Most public comment on the August 11, 2003 proposal supported requiring PWSs to correct significant deficiencies identified in sanitary surveys conducted by EPA. Commenters stated that requirements for sanitary surveys should be consistent for PWSs and should not depend on the primacy agency. EPA believes the requirements in today's final rule will establish this consistency.

One commenter requested that EPA include a process for PWSs to appeal a significant deficiency determination. EPA expects that PWSs will raise any concerns regarding significant deficiency determinations with the primacy agency, either the State or EPA, that conducts the sanitary survey. States or EPA may withdraw or amend their significant deficiency determinations as appropriate. The IESWTR did not establish a separate appeal process for sanitary surveys conducted by States, and EPA has not established such a process for sanitary surveys conducted by EPA under today's rule.

M. Variances and Exemptions

SDWA section 1415 allows States to grant variances from national primary drinking water regulations under certain conditions; section 1416 establishes the conditions under which States may grant exemptions to MCL or treatment technique requirements. These conditions and EPA's view on their applicability to the LT2ESWTR are summarized as follows:

1. Variances

Section 1415 specifies two provisions under which general variances to treatment technique requirements may be granted:

(1) A State that has primacy may grant a variance to a PWS from any requirement to use a specified treatment technique for a contaminant if the PWS demonstrates to the satisfaction of the State that the treatment technique is not necessary to protect public health because of the nature of the PWS's raw water source. EPA may prescribe monitoring and other requirements as conditions of the variance (section 1415(a)(1)(B)).

(2) EPA may grant a variance from any treatment technique requirement upon a showing by any person that an alternative treatment technique not included in such requirement is at least as efficient in lowering the level of the contaminant (section 1415(a)(3)).

EPA does not believe that the first variance provision is applicable to filtered PWSs under today's rule. Filtered PWSs are required to implement additional treatment under the LT2ESWTR only when source water monitoring demonstrates higher levels of Cryptosporidium contamination. Thus, this treatment technique requirement accounts for the nature of the PWS's raw water source. Unfiltered PWS treatment requirements also account for the nature of a PWS's raw water source with respect to whether 2- or 3-log Cryptosporidium inactivation is required.

In theory, the first variance provision could be applied to the requirement that all unfiltered PWSs provide at least 2-

log Cryptosporidium inactivation. If an unfiltered PWS could show a raw water Cryptosporidium level 3-log lower than the Bin 1 cutoff for filtered PWSs (i.e., below 0.075 oocysts/1,000 L), this could demonstrate that no treatment for Cryptosporidium is necessary. The unfiltered PWS would already be achieving public health protection against Cryptosporidium equivalent to filtered PWSs due to the nature of the raw water source.

In practice, EPA has not identified an approach that is economically or technologically feasible for a PWS to demonstrate such a low level of Cryptosporidium to support granting a variance. This is due to the extremely large volume and number of samples that would be necessary to make such a demonstration with confidence. However, unfiltered PWSs may choose to pursue the development and implementation of monitoring programs to apply for a variance from Cryptosporidium inactivation requirements based on the nature of the raw water source. A sufficient monitoring program may be feasible in site-specific circumstances or with the use of innovative approaches.

The second provision for granting a variance is not applicable to the LT2ESWTR because the rule provides broad flexibility in how PWSs achieve the required level of Cryptosporidium reduction through the microbial toolbox. Moreover, the microbial toolbox contains an option for Demonstration of Performance, under which States can award treatment credit based on the demonstrated efficiency of a treatment process in reducing Cryptosporidium levels. Thus, there is no need for this type of variance under the LT2ESWTR.

SDWA section 1415(e) describes small PWS variances, but these cannot be granted for a treatment technique for a microbial contaminant. Hence, small PWS variances are not allowed for the LT2ESWTR.

2. Exemptions

Under SDWA section 1416(a), a State may exempt any PWS from a treatment technique requirement upon a finding that (1) Due to compelling factors (which may include economic factors such as qualification of the PWS as serving a disadvantaged community), the PWS is unable to comply with the requirement or implement measures to develop an alternative source of water supply; (2) the PWS was in operation on the effective date of the treatment technique requirement, or for a PWS that was not in operation by that date, no reasonable alternative source of drinking water is available to the new PWS; (3) the exemption will not result in an unreasonable risk to health; and (4) management or restructuring changes (or both) cannot reasonably result in compliance with the Act or improve the quality of drinking water.

EPA believes that granting an exemption to the Cryptosporidium treatment requirements of the LT2ESWTR would result in an unreasonable risk to health. As described in section III.C, Cryptosporidium causes acute health effects, which may be severe in sensitive subpopulations and include risk of mortality. Moreover, the additional Cryptosporidium treatment requirements of the LT2ESWTR are targeted to PWSs with the highest degree of risk. Due to these factors, EPA does not support the granting exemptions from the LT2ESWTR.

V. State Implementation

A. Today's Rule

This section describes the regulations and other procedures and policies States must adopt to implement today's rule. States must continue to meet all other conditions of primacy in 40 CFR Part 142. To implement the LT2ESWTR, States must adopt revisions to the following sections:

§ 141.2—Definitions
Subpart Q—Public Notification
New Subpart W—Additional treatment technique requirements for Cryptosporidium
§ 142.14—Records kept by States
§ 142.15—Reports by States
§ 142.16—Special primacy requirements

1. Special State primacy requirements

To ensure that a State program includes all the elements necessary for an effective and enforceable program under today's rule, a State primacy application must include a description of how the State will perform the following:

- Approve an alternative to the E. coli levels that trigger Cryptosporidium monitoring by filtered systems serving fewer than 10,000 people (see section IV.A.1);
- Approve watershed control programs for the 0.5 log watershed control program credit in the microbial toolbox (see section IV.D.2);
- Assess significant changes in the watershed and source water as part of the sanitary survey process and determine appropriate follow-up action (see section IV.A); and
- Approve protocols for treatment credit under the Demonstration of Performance toolbox option (see section IV.D.9), for site specific chlorine dioxide and ozone CT tables (see section IV.D.14), and for alternative UV reactor validation testing (see section IV.D.15).

A State program can be more, but not less, stringent than Federal regulations. As such, some of the elements listed here may not be applicable to a specific State program.

2. State Recordkeeping Requirements

Today's rule requires States to keep additional records of the following, including all supporting information and an explanation of the technical basis for each decision:

- Results of source water E. coli and Cryptosporidium monitoring for not less than 1 year;
- Cryptosporidium treatment bin classification for each filtered PWS after the initial and after the second round of source water monitoring. Also, any change in treatment requirements for filtered systems due to watershed assessment during sanitary surveys;
- Determination of whether each unfiltered PWS has a mean source water Cryptosporidium level above 0.01 oocysts/L after the initial and after the second round of source water monitoring;
- The treatment processes or control measures that each PWS employs to meet Cryptosporidium treatment requirements under the LT2ESWTR, including measures that systems may use for only part of the year; and
- A list of PWSs required to cover or treat the effluent of an uncovered finished water storage facilities.

3. State Reporting Requirements

Today's rule requires States to report the following information:

- The Cryptosporidium treatment bin classification for each filtered PWS after the initial and after the second round of source water monitoring. Also, any change in treatment requirements for filtered systems due to watershed assessment during sanitary surveys; and
- The determination of whether each unfiltered PWS has a mean source water Cryptosporidium level above 0.01 oocysts/L after the initial and after the second round of source water monitoring.

4. Interim Primacy

States that have primacy (including interim primacy) for every existing NPDWR already in effect may obtain interim primacy for this rule, beginning on the date that the State submits the application for this rule to USEPA, or the effective date of its revised regulations, whichever is later. A State that wishes to obtain interim primacy

for future NPDWRs must obtain primacy for today's rule. As described in Section IV.A, EPA expects to work with States to oversee the initial source water monitoring that begins six months following rule promulgation.

B. Background and Analysis

SDWA establishes requirements that a State or eligible Indian Tribe must meet to assume and maintain primary enforcement responsibility (primacy) for its PWSs. These requirements include the following activities: (1) Adopting drinking water regulations that are no less stringent than Federal drinking water regulations; (2) adopting and implementing adequate procedures for enforcement; (3) keeping records and making reports available on activities that EPA requires by regulation; (4) issuing variances and exemptions (if allowed by the State), under conditions no less stringent than allowed under SDWA; and (5) adopting and being capable of implementing an adequate plan for the provisions of safe drinking water under emergency situations.

40 CFR part 142 sets out the specific program implementation requirements for States to obtain primacy for the public water supply supervision program as authorized under SDWA section 1413. In addition to adopting basic primacy requirements specified in 40 CFR Part 142, States may be required to adopt special primacy provisions pertaining to specific regulations where implementation of the rule involves activities beyond general primacy provisions. States must include these regulation specific provisions in an application for approval of their program revision.

The current regulations in 40 CFR 142.14 require States with primacy to keep various records, including the following: analytical results to determine compliance with MCLs, MRDLs, and treatment technique requirements; PWS inventories; State approvals; enforcement actions; and the issuance of variances and exemptions. Today's final rule requires States to keep additional records, including all supporting information and an explanation of the technical basis for decisions made by the State regarding today's rule requirements. EPA currently requires in 40 CFR 142.15 that States report to EPA information such as violations, variance and exemption status, and enforcement actions, and today's rule adds additional reporting requirements related to monitoring and treatment requirements.

On April 28, 1998, EPA amended its State primacy regulations at 40 CFR 142.12 to incorporate the new process identified in the 1996 SDWA Amendments for granting primary enforcement authority to States while their applications to modify their primacy programs are under review (63 FR 23362, April 28, 1998) (USEPA 1998c). The new process grants interim primary enforcement authority for a new or revised regulation during the period in which EPA is making a determination with regard to primacy for that new or revised regulation. This interim enforcement authority begins on the date of the primacy application submission or the effective date of the new or revised State regulation, whichever is later, and ends when EPA makes a final determination. However, this interim primacy authority is only available to a State that has primacy (including interim primacy) for every existing NPDWR in effect when the new regulation is promulgated. States that have primacy for every existing NPDWR already in effect may obtain interim primacy for this rule and a State that wishes to obtain interim primacy for future NPDWRs must obtain primacy for this rule.

C. Summary of Major Comments

Public comment generally supported the special primacy requirements in the August 11, 2003 proposal, and many commenters expressed appreciation for the flexibility the special primacy requirements provided to States. One commenter expressed concern that a State that adopted this rule by reference would lose the flexibility intended in the proposal. In response, EPA recognizes that some States may be limited by their statutes in applying the flexibility allowed under today's rule. However, EPA believes that providing flexibility for States to approve site-specific approaches that achieve the public health goals of the LT2ESWTR is appropriate and will benefit some States and PWSs.

A few commenters were concerned that the special primacy requirement to assess changes in watersheds as part of the sanitary survey process would be difficult to meet due to a lack of resources or large watersheds that overlap State boundaries. In response, EPA notes that States are required to evaluate PWS sources under the existing sanitary survey requirements (40 CFR 142.16(b)(3)). If a State determines during a sanitary survey that significant changes have occurred in the watershed that could lead to increased contamination of the source by Cryptosporidium, today's rule gives the State the authority to require the PWS to take actions to mitigate or treat the contamination. Because the treatment requirements in today's rule depend on the degree of source water contamination, EPA believes that this assessment of changes in a PWS's source water following initial bin classification is necessary.

EPA also received comments on State approval processes for laboratories analyzing for Cryptosporidium to meet LT2ESWTR requirements. Most commenters stated that EPA should maintain a national certification program for laboratories approved for Cryptosporidium analysis for LT2ESTWR compliance. Commenters indicated that requiring States to approve laboratories for Cryptosporidium analysis placed too great a demand on State resources. Today's rule does not include a State primacy requirement for laboratory certification for Cryptosporidium analysis.

Some commenters were concerned with the data tracking and review burden on States from the reporting requirements for the individual toolbox components. EPA agrees with commenters that, in some cases, allowing PWSs to report summaries or to self-certify that the PWS met the performance requirements for microbial toolbox treatment credit may be appropriate. Today's rule allow States to modify the level of reporting required for toolbox components and specifically, permit PWSs to self-certify to the State that a toolbox component has met its performance requirements.

VI. Economic Analysis

This section summarizes the economic analysis (EA) for the final LT2ESWTR. The EA is an assessment of the benefits, both health and nonhealth-related, and costs to the regulated community of the final regulation, along with those of regulatory alternatives that the Agency considered. EPA developed the EA to meet the requirement of SDWA section 1412(b)(3)(C) for a Health Risk Reduction and Cost Analysis (HRRCA), as well as the requirements of Executive Order 12866, Regulatory Planning and Review, under which EPA must estimate the costs and benefits of the LT2ESWTR. The full EA is presented in Economic Analysis for the Long Term 2 Enhanced Surface Water Treatment Rule (USEPA 2005a), which includes additional details and discussion on the topics presented throughout this section of the preamble.

The LT2ESWTR is the second in a staged set of rules that address public health risks from microbial contamination of surface and GWUDI drinking water supplies and, more specifically, prevent Cryptosporidium

from reaching consumers. As described in section III, EPA promulgated the IESWTR and LT1ESWTR to provide a baseline of protection against Cryptosporidium in large and small PWSs, respectively. Today's final rule will achieve further reductions in Cryptosporidium exposure for PWSs with the highest vulnerability. This EA considers only the incremental reduction in exposure beyond the two previously promulgated rules (IESWTR and LT1ESWTR) from the alternatives evaluated for the LT2ESWTR.

A. What Regulatory Alternatives Did the Agency Consider?

Regulatory alternatives considered by the Agency for the LT2ESWTR were developed through the deliberations of the Stage 2 M–DBP Federal Advisory Committee (described in section III). The Advisory Committee considered several general approaches for reducing the risk from Cryptosporidium in drinking water. These approaches included both additional treatment requirements for all PWSs and risk-targeted treatment requirements for PWSs with the highest vulnerability to Cryptosporidium following implementation of the IESWTR and LT1ESWTR. In addition, the Advisory Committee considered related issues such as alternative monitoring strategies.

After considering these general approaches, the Advisory Committee focused on four regulatory alternatives for filtered PWSs (see Table VI.A–1). With the exception of Alternative 1, which requires all PWSs to provide additional treatment for Cryptosporidium, these alternatives incorporate a risk-targeting approach in which PWSs are classified in different treatment bins based on the results of source water monitoring. Additional Cryptosporidium treatment requirements are directly linked to the treatment bin classification. Accordingly, these rule alternatives are differentiated by two criteria: (1) The Cryptosporidium concentrations that define the bin boundaries and (2) the degree of treatment required for each bin.

The Advisory Committee reached consensus regarding additional treatment requirements for unfiltered PWSs without formally identifying regulatory alternatives other than requiring no treatment for Cryptosporidium (i.e., no new regulation).

TABLE VI.A–1.—SUMMARY OF REGULATORY ALTERNATIVES FOR FILTERED PWSS

Mean source water Cryptosporidium monitoring result (oocysts/L)	Additional treatment requirements [1]
Alternative A1	
2.0-log inactivation required for all PWSs	
Alternative A2	
< 0.03	No additional treatment.
≥ 0.03 and < 0.1	0.5-log.
≥ 0.1 and < 1.0	1.5-log.
≥ 1.0	2.5-log.
Alternative A3—Today's Final Rule	
< 0.075	No additional treatment.
≥ 0.075 and < 1.0	1-log.
≥ 1.0 and < 3.0	2-log.
≥ 3.0	2.5-log.
Alternative A4	
< 0.1	No additional treatment.
≥ 0.1 and < 1.0	0.5-log.
≥1.0	1.0-log.

[1] Note: ''Additional treatment requirements'' are in addition to levels already required under existing rules (e.g., the IESWTR and LT1ESWTR) for PWSs using conventional treatment or equivalent.

B. What Analyses Support Today's Final Rule?

EPA has quantified benefits and costs for each of the filtered PWS regulatory alternatives in Table VI.A–1 and for unfiltered PWS requirements. Quantified benefits stem from estimated reductions in the incidence of cryptosporidiosis resulting from the regulation. To make these estimates, the Agency employed Monte Carlo modeling to account for uncertainty and variability in key parameters like Cryptosporidium occurrence, infectivity, and treatment efficiency. Costs result largely from the installation of additional treatment, with lesser costs due to monitoring and other implementation activities.

Cryptosporidium occurrence significantly influences the estimated benefits and costs of regulatory alternatives. As discussed in section III.E, EPA analyzed data collected under the ICR, the ICR Supplemental Surveys of medium PWSs (ICRSSM), and the ICR Supplemental Surveys of large PWSs (ICRSSL) to estimate the national occurrence distribution of Cryptosporidium in surface water. EPA evaluated these distributions independently when assessing benefits and costs for different regulatory alternatives.

Another parameter that significantly influences estimated benefits is Cryptosporidium infectivity (i.e., the likelihood of infection after exposure to a given dose of Cryptosporidium). As discussed in section III.E, EPA considered results from human volunteer feeding studies and applied six different model forms to estimate dose-response relationships.

To address uncertainty in these estimates, benefits are presented for three different dose response models: A ''high'' estimate based on the model that showed the highest mean baseline risk, a ''medium'' estimate based on the model and data used at proposal, which is in the middle of the range of estimates produced by the six models, and a ''low'' estimate, based on the model that showed the lowest mean baseline risk. These estimates are not upper and lower bounds. For each model, a distribution of effects is estimated, and the ''high'' and ''low'' estimates show only the means of these distributions for two different model choices.

Both benefits and costs are determined as annualized present values, which allows comparison of cost and benefit streams that are variable over time. The time frame used for both benefit and cost comparisons is 25 years. The Agency uses social discount rates of both 3 percent and 7 percent to calculate present values from the stream of benefits and costs and also to annualize the present value estimates over 25 years (see EPA's Guidelines for Preparing Economic Analyses (USEPA 2000c) for a discussion of social discount rates).

Results of these analyses are summarized in this section of the preamble. Detailed results and descriptions of the supporting analyzes are shown in the LT2ESWTR EA (USEPA 2005a).

In evaluating the regulatory alternatives shown in Table VI.A–1, EPA and the Advisory Committee were concerned with the following questions: (1) Do the treatment requirements adequately control Cryptosporidium concentrations in finished water? (2) How many PWSs will be required to add treatment? and (3) What is the likelihood that PWSs will be misclassified in higher or lower treatment bins through monitoring?

Consistent with the consensus recommendation of the Advisory Committee, EPA selected Alternative A3 for today's final rule. EPA has determined that this alternative will significantly reduce the incidence of cryptosporidiosis due to drinking water

in vulnerable PWSs and is feasible for PWSs to implement.

Alternative A1 (across-the-board 2-log inactivation) was not selected because it would impose costs but provide few benefits to PWSs with relatively low Cryptosporidium risk. EPA was also concerned about the feasibility of requiring every surface water treatment plant to install additional treatment processes (e.g., UV) for Cryptosporidium. With Alternative A2, EPA was concerned with the feasibility of accurately classifying PWSs in treatment bins at a Cryptosporidium concentration of 0.03 oocysts/L. EPA does not believe that Alternative A4 would reduce risks from Cryptosporidium in vulnerable PWSs to the extent feasible, as required under SDWA section 1412(b)(7)(A), because of the low levels of treatment required.

C. What Are the Benefits of the LT2ESWTR?

EPA has quantified and monetized health benefits for reductions in endemic cryptosporidiosis due to the LT2ESWTR. In addition, today's rule is expected to provide additional health and nonhealth-related benefits that EPA was unable to quantify. Table VI.C–1 summarizes these unquantified benefits.

1. Nonquantified Benefits

TABLE VI.C–1.—SUMMARY OF NONQUANTIFIED BENEFITS

Benefit type	Potential effect on benefits	Comments
Reducing outbreak risks and response costs.	Increase	Some human or equipment failures may occur even with the requirements of today's rule; however, by adding barriers of protection for some PWSs, the rule will reduce the possibility of such failures leading to outbreaks.
Reducing averting behavior (e.g., boiling tap water or purchasing bottled water).	Increase/No Change	Consumers in PWSs that cease using uncovered finished water reservoirs (through covering or taking such reservoirs off-line) may have greater confidence in water quality. This may result in less averting behavior that reduces both out-of-pocket costs (e.g., purchase of bottled water) and opportunity costs (e.g., time to boil water).
Improving aesthetic water quality	Increase	Some technologies installed for this rule (e.g., ozone) are likely to reduce taste and odor problems.
Reducing risk from co-occurring and emerging pathogens.	Increase	Although focused on removal of Cryptosporidium from drinking water, PWSs that change treatment processes will also increase removal of pathogens that the rule does not specifically regulate.
Increased source water monitoring	Increase	The greater understanding of source water quality that results from monitoring may enhance the ability of plants to optimize treatment operations in ways other than those addressed in this rule.
Reduced contamination due to covering or treating finished water storage facilities.	Increase	Contaminants introduced through uncovered finished water storage facilities will be reduced, which will produce positive public health benefits.
Change in the levels of disinfection byproducts.	Increase/Decrease	PWSs that install ozone to comply with the LT2ESWTR may experience an increase in certain DBPs. PWSs that install UV or microfiltration may reduce the use of chlorine and experience a decrease in DBPs.

Source: Chapter 5 of the LT2ESWTR Economic Analysis (USEPA 2005a).

2. Quantified Benefits

In quantifying benefits for the LT2ESWTR based on reductions in the risk of endemic cryptosporidiosis, EPA considered several categories of monetized benefits. First, EPA estimated the number of cases expected to result in premature mortality (primarily for members of sensitive subpopulations such as AIDS patients). The mortality estimate was developed using data from the Milwaukee cryptosporidiosis outbreak of 1993 (described in section III), with adjustments to account for the subsequent decrease in the mortality rate among people with AIDS and for the difference between the portion of people living with AIDS in 1993 in Milwaukee and the current and projected national levels. EPA estimated a mortality rate of 26.3 deaths per 100,000 illnesses for those served by unfiltered PWSs and a mortality rate of 16.7 deaths per 100,000 illnesses for those served by filtered PWSs. These different rates are associated with the incidence of AIDS in populations served by unfiltered and filtered PWSs. A complete discussion on how EPA derived these rates can be found in subchapter 5.2 of the LT2ESWTR EA (USEPA 2005a).

Reductions in mortalities were monetized using EPA's standard methodology for monetizing mortality risk reduction. This methodology is based on a distribution of value of statistical life (VSL) estimates from 26 labor market and stated preference studies. The mean VSL is $7.4 million in 2005 with a 5th to 95th percentile range of $1.2 to $16.9 million. A more detailed discussion of these studies and the VSL estimate can be found in EPA's Guidelines for Preparing Economic Analyses (USEPA 2000c). A real income growth factor was applied to these estimates of approximately 1.9 percent per year for the 20-year time span following implementation. Income elasticity for VSL was estimated as a triangular distribution that ranged from 0.08 to 1.00, with a mode of 0.40. VSL values for the 20-year span are shown in the LT2ESWTR EA in Exhibit 5.24 (USEPA 2005a).

The substantial majority of cases are not expected to be fatal and the Agency separately estimated the value of non-fatal illnesses avoided that would result from the LT2ESWTR. For these, EPA first divided projected cases into three categories, mild, moderate, and severe, and then calculated a monetized value per case avoided for each severity level. These were then combined into a weighted average value per case based on the relative frequency of each severity level. According to a study conducted by Corso et al. (2003), the majority of illness fall into the mild category (88 percent). Approximately 11 percent of illness fall into the moderate category, which is defined as those who seek medical treatment but are not hospitalized. The final 1 percent have severe symptoms that result in hospitalization. EPA estimated different medical expenses and time losses for each category.

Benefits for non-fatal cases were calculated using a cost-of-illness (COI)

approach. Traditional COI valuations focus on medical costs and lost wages, and leave out significant categories of benefits, specifically the reduced utility from being sick (i.e., lost personal or non-work time, including activities such as child care, homemaking, community service, time spent with family, recreation, and pain and suffering), although some COI studies also include an estimate for unpaid labor (household production) valued at an estimated wage rate designed to reflect the market value of such labor (e.g., median wage for household domestic labor). Ideally, a comprehensive willingness to pay (WTP) estimate would be used that includes all categories of loss in a single number. However, a review of the literature indicated that the available studies were not suitable for valuing cryptosporidiosis; hence, estimates from this literature are inappropriate for use in this analysis. Instead, EPA presents two COI estimates: A traditional approach that only includes valuation for medical costs and lost work time (including some portion of unpaid household production); and an enhanced approach that also factors in valuations for lost unpaid work time for employed people, reduced utility (or sense of well-being) associated with decreased enjoyment of time spent in non-work activities, and lost productivity at work on days when paid workers are ill but go to work anyway.

Table VI.C–2 shows the various categories of loss and how they were valued for each estimate for a ''typical'' case in 2003 (weighted average based on severity level).

TABLE VI.C–2.—TRADITIONAL AND ENHANCED COI FOR CRYPTOSPORIDIOSIS, 2003$

[Weighted average cost per case]

Loss category	Traditional COI	Enhanced COI
Direct Medical Costs	$106.91	106.91
Lost Paid Work Days	120.13	120.13
Lost Unpaid Work Days [1]	24.32	48.64
Lost Leisure Time [2]	not included	217.79
Lost Caregiver Days [3]	22.98	61.50
Lost Leisure Productivity [4]	not included	162.98
Lost Productivity at Work	not included	126.29
Total	274.34	844.24

[1] Assigned to 39.7% of the population not engaged in market work; assumes 40 hr. unpaid work week, valued at $6.23/hr in traditional COI and $12.46/hr in enhanced COI. Does not include lost unpaid work for employed people and may not include all unpaid work for people outside the paid labor force.

[2] Includes child care and homemaking (to the extent not covered in lost unpaid work days above), time with family, and recreation for people within and outside the paid labor force, on days when subject is too sick to work.

[3] Values lost work or leisure time for people caring for the ill. Traditional approach does not include lost leisure time. Detail may not calculate to totals due to independent rounding; Source: Appendix L in LT2ESWTR EA (USEPA 2005a)

[4] Analogous to lost productivity at work. Includes reduced productivity in unpaid work and reduced enjoyment of recreation on days when subject is sick but engages in unpaid work or leisure activities anyway.

The various loss categories were calculated as follows: Medical costs are a weighted average across the three illness severity levels of actual costs for doctor and emergency room visits, medication, and hospital stays. Lost paid work represents missed work time of paid employees, valued at the median pre-tax wage, plus benefits, of $20.82 hour. The average number of lost work hours per illness day is 3.4 (this assumes that 60 percent of the population is in the paid labor force and the loss is averaged over 7 days). The weighted average number of lost work days per case is 1.7 days. Medical costs and lost work days reflect market transactions. Medical costs are always included in COI estimates and lost work days are usually included in COI estimates.

In the traditional COI estimate, an equivalent amount of lost unpaid work time was assigned to the 40 percent of the population that are not in the paid labor force. This includes homemakers, students, children, retires, and unemployed persons. This estimate attempts to capture market-like work (e.g., homemaking, volunteer work) that is unpaid. EPA did not attempt to calculate what percent of cases falls in each of these five groups, or how many hours per week each group works, but rather assumed an across-the-board 40 hour unpaid work week. For this reason, it likely overstates the value of unpaid, market-like work, but EPA does not have data on this. This time is valued at $6.23 per hour, which is one half the median post-tax wage (since work performed by these groups is not taxed). This is also approximately the median wage for paid household domestic labor.

In the enhanced COI estimate, an estimate of lost unpaid work days for people outside the paid labor force was made by assigning the value of $12.46 per hour to the same number of unpaid work hours valued in the traditional COI approach (i.e., 40 unpaid work hours per week). Lost unpaid work for employed people and any unpaid labor beyond 40 hours per week for those not in the labor market is shown as lost leisure time in Table VI.C–2 for the enhanced approach and is not included in the traditional approach.

In the enhanced approach, all time other than paid and market-like work and sleep (8 hours per work day and 16 hours per non-work day) is valued at the median after tax wage, or $12.46 per hour. This includes lost unpaid personal work (e.g., chores, errands, housework) and leisure time for people within and outside the paid labor force. The average number of unpaid work hours per illness day is 2.3 (40 hours per week averaged over 7 days $\times$ 40 percent of the population). Implicit in this approach is that people would pay the same amount not to be sick during their leisure time as they require to give up their leisure time to work (i.e., the after tax wage). In reality, people might be willing to pay either more than this amount (if they were very sick and suffering a lot) or less than this amount (if they were not very sick and still got some enjoyment out of activities such as resting, reading, and watching TV), not to be sick. Multiplying 10.3 hours by $12.46 gives a value of about $128 for a day of ''lost'' unpaid personal work and leisure (i.e., lost utility of being sick). The weighted average number of lost leisure days per case is the same as the weighted average number of lost work days (1.7 days per case).

In addition, for days when an individual is well enough to work but is still experiencing symptoms, such as diarrhea, the enhanced estimate also includes a 30 percent loss of work and leisure productivity, based on a study of giardiasis illness (Harrington et al. 1985), which is similar to cryptosporidiosis. Appendix P in the EA describes similar productivity losses for other illnesses such as influenza (35%–73% productivity losses). In the traditional COI analysis, productivity losses are not included for either work or nonwork time. The weighted average number of reduced productivity days per case, for both work and leisure, is 1.3 days.

EPA believes that losses in productivity and lost leisure time are unquestionably present and that these categories have positive value; consequently, the traditional COI estimate understates the true value of these loss categories. EPA notes that these estimates should not be regarded as upper and lower bounds. In particular, the enhanced COI estimate may not fully incorporate the value of pain and suffering, as people may be willing to pay more than $228 (the sum of the valuation of lost work and leisure) to avoid a day of illness. The traditional COI estimate may not be a lower bound because it includes a valuation for a lost 40 hour work week for all persons not in the labor force, including children and retirees. This may be an overstatement of lost productivity for these groups, which would depend on the impact of such things as missed school work or volunteer activities that may be affected by illness.

As with the avoided mortality valuation, the real wages used in the COI estimates were increased by a real income growth factor that varies by year, but is the equivalent of about 1.9 percent over the 20 year period. This approach of adjusting for real income growth was recommended by the SAB (USEPA 2000d) because the median real wage is expected to grow each year (by approximately 1.9 percent). Correspondingly, the real income growth factor of the COI estimates increases by the equivalent of 1.9 percent per year (except for medical costs, which are not directly tied to wages). This approach gives a total COI valuation per case in 2010 of $306 (undiscounted) for the traditional COI estimate and $985 (undiscounted) for the enhanced COI estimate; the valuation in 2029 is $381 (undiscounted) for the traditional COI estimate and $1,316 (undiscounted) for the enhanced COI estimate. There is no difference in the methodology for calculating the COI over this 20 year period of implementation; the change in valuation is due to the underlying change in projected real wages.

Table VI.C–3 summarizes the annual cases of cryptosporidiosis illness and associated deaths avoided due to the LT2ESWTR proposal. Today's rule, on average, is expected to reduce 89,375 to 1,459,126 illnesses and 20 to 314 deaths annually after full implementation (range based on the ICRSSL, ICRSSM, and ICR data sets and model choice for Cryptosporidium infectivity).

Table VI.C-3.–Summary of Annual Avoided Illness and Deaths

Data Set	Annual Illnesses Avoided			Annual Deaths Avoided		
	Low	Medium	High	Low	Medium	High
Total after Full implementation						
ICR	358,732	964,360	1,459,126	76	207	314
ICRSSL	89,375	230,730	372,507	20	52	84
ICRSSM	177,101	455,170	711,123	39	100	156
Annual Average over 25 years						
ICR	264,980	712,732	1,078,796	57	154	232
ICRSSL	66,187	170,977	276,078	15	39	62
ICRSSM	130,918	336,652	438,203	29	74	116

Source: The LT2ESWTR Economic Analysis (USEPA 2005a)
Note: High, medium, and low estimates reflect the mean estimates for a range of dose-response modeling assumptions. See Appendix N of the LT2ESWTR Economic Analysis (USEPA, 2005a).

Tables VI.C–4a and VI.C–4b show the monetized present value of the benefit for reductions in endemic cryptosporidiosis estimated to result from the LT2ESWTR for the enhanced and traditional COI values, respectively. Estimates are given for the ICR, ICRSSL, and ICRSSM occurrence data sets and for the three infectivity models.

With the enhanced COI and a 3 percent discount rate, the annual present value of the mean benefit estimate ranges from $177 million to $2.8 billion; at a 7 percent discount rate, the mean estimate ranges from $144 million to $2.3 billion. With the traditional COI, the corresponding mean benefit estimate at a 3 percent discount rate ranges from $130 million to $2.0 billion; for a 7 percent discount rate, the mean estimate ranges from $105 million to $1.7 billion. None of these values include the unquantified and nonmonetized benefits listed in Table VI.C–1.

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Table VI.C-4a.–Summary of Quantified Benefits—Enhanced COI[1] ($millions, 2003$)

Data Set	Value of Benefits ($ Millions, 2003$)		
	Low	Medium	High
Annualized Value (at 3%, 25 Years)			
ICR	$ 687	$ 1,853	$ 2,822
ICRSSL	$ 177	$ 458	$ 744
ICRSSM	$ 344	$ 886	$ 1,393
Annualized Value (at 7%, 25 Years)			
ICR	$ 556	$ 1,501	$ 2,286
ICRSSL	$ 144	$ 371	$ 603
ICRSSM	$ 279	$ 718	$ 1,128

Table VI.C-4b.--Summary of Quantified Benefits—Traditional COI[1] ($Millions, 2003$)

Data Set	Value of Benefits ($ Millions, 2003$)		
	Low	Medium	High
Annualized Value (at 3%, 25 Years)			
ICR	$ 497	$ 1,341	$ 2,047
ICRSSL	$ 130	$ 335	$ 546
ICRSSM	$ 250	$ 644	$ 1,014
Annualized Value (at 7%, 25 Years)			
ICR	$ 403	$ 1,089	$ 1,662
ICRSSL	$ 105	$ 272	$ 443
ICRSSM	$ 203	$ 523	$ 824

[1]The traditional COI only includes valuation for medical costs and lost work time (including some portion of unpaid household production and other market like work). The enhanced COI also factors in valuations for lost personal time (non-worktime) such as child care and homemaking (to the extent not covered by the traditional COI), time with family, and recreation, and lost productivity in both work and leisure on days when workers are ill but go to work anyway. Source: The LT2ESWTR Economic Analysis (USEPA 2005a)

Note: High, medium, and low estimates reflect the mean estimates for a range of dose-response modeling assumptions. See Appendix N of the LT2ESWTR Economic Analysis (USEPA. 2005a)

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a. *Filtered PWSs.* Benefits to the approximately 168 million people served by filtered surface water and GWUDI PWSs range from 34,000 to 702,000 reduction in mean annual cases of endemic illness based on three infectivity models and ICRSSL, ICRSSM, and ICR data sets. In addition, premature mortality is expected to be reduced by an average of 6 to 116 deaths annually.

b. *Unfiltered PWSs.* The 10 million people served by unfiltered surface water or GWUDI PWSs will see a significant reduction in cryptosporidiosis as a result of the LT2ESWTR. In this population, the rule is expected to reduce approximately 55,000 to 758,000 cases of illness and 14 to 197 premature deaths annually.

For unfiltered PWSs, only the ICR data set is used to directly calculate illness reduction because it is the only data set that includes sufficient information on unfiltered PWSs. Illness reduction in unfiltered PWSs was estimated for the ICRSSL and ICRSSM

data sets by multiplying the ICR unfiltered PWS result by the ratio, for the quantity estimated, between filtered PWS results from the supplemental survey data set (SSM or SSL) and filtered PWS results from the ICR.

3. Timing of Benefits Accrual (latency)

In previous rulemakings, some commenters have argued that the Agency should consider an assumed time lag or latency period in its benefits calculations. The Agency has not conducted a latency analysis for this rule because cryptosporidiosis is an acute illness; therefore, very little time elapses between exposure, illness, and mortality. However, EPA does account for benefits and costs that occur in future years by converting these to present value estimates.

D. What Are the Costs of the LT2ESWTR?

In order to estimate the costs of today's rule, the Agency considered impacts on PWSs and on States (including territories and EPA implementation in non-primacy States). Summary information on these costs follows, with more detailed information in chapter 6 of the LT2ESWTR EA (USEPA 2005a). A detailed discussion of the requirements of today's rule is located in section IV of this preamble.

1. Total Annualized Present Value Costs

Tables VI.D–1 summarizes the annualized present value cost estimates for the LT2ESWTR at 3 percent and 7 percent discount rates. The mean annualized present value costs of the LT2ESWTR are estimated to range from approximately $93 to $133 million using a 3 percent discount rate and $107 to $150 million using a 7 percent discount rate. This range in mean cost estimates is associated with the different Cryptosporidium occurrence data sets. In addition to mean estimates of costs, the Agency calculated 90 percent confidence bounds by considering the uncertainty in Cryptosporidium occurrence estimates and the uncertainty around the mean unit technology costs (USEPA 2005a).

PWSs will incur approximately 99 percent of the rule's total annualized present value costs. States incur the remaining rule costs. Table VI.D–2 shows the undiscounted initial capital and one-time costs broken out by rule component. A comparison of annualized present value costs among the rule alternatives considered by the Agency is located in section VI.F of this preamble.

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Table VI.D-1.– Annualized Present Value Costs for the LT2ESWTR ($millions, 2003$)

	ICR			ICRSSL			ICRSSM		
		Confidence Bounds			Confidence Bounds			Confidence Bounds	
	Mean	5th %ile	95th %ile	Mean	5th %ile	95th %ile	Mean	5th %ile	95th %ile
	3%								
National	$ 133.42	$ 111.05	$ 160.00	$ 92.88	$ 72.11	$ 112.17	$ 105.90	$ 86.30	$ 125.74
System Total	$ 132.27	$ 109.91	$ 158.83	$ 91.78	$ 71.03	$ 111.07	$ 104.79	$ 85.20	$ 124.62
State Total	$ 1.15	$ 1.14	$ 1.17	$ 1.09	$ 1.08	$ 1.10	$ 1.11	$ 1.10	$ 1.12
	7%								
National	$ 150.48	$ 125.12	$ 180.61	$ 106.77	$ 83.21	$ 128.83	$ 120.93	$ 98.58	$ 143.61
System Total	$ 149.07	$ 123.72	$ 179.19	$ 105.42	$ 81.87	$ 127.47	$ 119.56	$ 97.22	$ 142.23
State Total	$ 1.41	$ 1.39	$ 1.42	$ 1.35	$ 1.34	$ 1.36	$ 1.37	$ 1.36	$ 1.38

Source: Chapter 6 of the *LT2ESWTR Economic Analysis* (USEPA 2005a)

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Table VI.D-2.–Initial Capital and One-time Costs for the LT2ESWTR ($millions, 2003$)

	Serving < 10,000 People			Serving ≥ 10,000 People			All Systems		
Type of Cost	ICR	ICRSSL	ICRSSM	ICR	ICRSSL	ICRSSM	ICR	ICRSSL	ICRSSM
Total									
National (System + State)							$2,104.32	$ 1,526.27	$ 1,719.41
System									
System Total	$ 214.30	$ 132.32	$ 157.93	$ 1,869.74	$ 1,373.81	$ 1,541.30	$2,084.04	$ 1,506.13	$ 1,699.23
Treatment	$ 140.74	$ 76.26	$ 94.75	$ 1,706.86	$ 1,208.24	$ 1,376.73	$1,847.60	$ 1,284.50	$ 1,471.48
Implementation	$ 1.19	$ 1.19	$ 1.19	$ 0.39	$ 0.39	$ 0.39	$ 1.59	$ 1.59	$ 1.59
Initial Monitoring	$ 38.03	$ 28.27	$ 32.07	$ 26.77	$ 26.77	$ 26.77	$ 64.80	$ 55.04	$ 58.84
Second Monitoring	$ 33.47	$ 26.05	$ 29.30	$ 18.01	$ 20.97	$ 19.86	$ 51.48	$ 47.02	$ 49.16
Benchmarking	$ 0.07	$ 0.04	$ 0.05	$ 0.08	$ 0.06	$ 0.07	$ 0.16	$ 0.10	$ 0.11
Tech Reporting	$ 0.65	$ 0.37	$ 0.43	$ 0.74	$ 0.49	$ 0.58	$ 1.39	$ 0.86	$ 1.01
Uncovered Reservoirs	$ 0.14	$ 0.14	$ 0.14	$ 116.88	$ 116.88	$ 116.88	$ 117.03	$ 117.03	$ 117.03
State									
State Total							$ 20.28	$ 20.15	$ 20.19
Implementation							$ 7.77	$ 7.77	$ 7.77
Initial Monitoring							$ 5.98	$ 5.98	$ 5.98
Second Monitoring							$ 6.18	$ 6.18	$ 6.18
Benchmarking							$ 0.09	$ 0.06	$ 0.07
Tech Reporting							$ 0.27	$ 0.17	$ 0.19
Uncovered Reservoirs							$ 0.00	$ 0.00	$ 0.00

Source: Chapter 6 of the *LT2ESWTR Economic Analysis* (USEPA 2005a)

2. PWS Costs

Table VI.D–3 shows the number of filtered and unfiltered PWSs that will incur costs by rule provision. All PWSs that treat surface water or GWUDI (*i.e.*, nonpurchased PWSs) will incur one-time costs that include time for staff training on rule requirements. PWSs will incur monitoring costs to assess source water Cryptosporidium levels, though monitoring requirements vary by PWS size (large vs. small) and PWS type (filtered vs. unfiltered). Some PWSs will incur costs for additional Cryptosporidium treatment, where required, and for covering or treating uncovered finished water reservoirs.

Table VI.D-3.– Number of Filtered and Unfiltered PWSs and Plants Expected to Incur Monitoring and Treatment Costs[1]

	Nonpurchased Systems and Plants							
			Source Water Monitoring - Plants					
Dataset	System Size (population served)	Systems Incurring Implementation Costs	Initial *E. Coli* Monitoring	Initial *Crypto* Monitoring	Future *E. coli* Monitoring	Future *Crypto* Monitoring	Plants Adding Treatment	Systems with Uncovered Reservoirs
		A	B	C	D	E	F	G
ICR	< 10,000	5,663	5,575	1,978	4,977	1,732	2,205	12
	≥ 10,000	1,493	1,733	1,762	1,184	1,184	677	69
	Total	7,156	7,308	3,741	6,161	2,916	2,882	81
ICRSSL	< 10,000	Same as ICR		1,285	5,237	1,171	1,428	
	≥ 10,000			1,762	1,379	1,379	440	Same as ICR
	Total			3,047	6,615	2,550	1,868	
ICRSSM	< 10,000	Same as ICR		1,555	5,181	1,409	1,729	
	≥ 10,000			1,762	1,306	1,306	531	Same as ICR
	Total			3,317	6,487	2,715	2,260	

[1]Numbers shown for plants monitoring include nonpurchased plants only. Numbers shown for plants adding treatment include both nonpurchased plants and a fraction of plants purchasing water that could not be linked to their wholesale plant. Source: Chapter 6 of the *LT2ESWTR Economic Analysis* (USEPA 2005a)

a. *Source water monitoring costs.* Source water monitoring costs are structured on a per-plant basis. There are three types of monitoring that plants may be required to conduct—turbidity, E. coli, and Cryptosporidium. Source water turbidity is a common water quality parameter used for plant operational control. Also, to meet SWTR, LT1ESWTR, and IESWTR requirements, most PWSs have turbidity analytical equipment in-house and operators are experienced with turbidity measurement. Thus, EPA assumes that the incremental turbidity monitoring burden associated with the LT2ESWTR is negligible.

Filtered plants in small PWSs initially will be required to conduct 1 year of biweekly E. coli source water monitoring. These plants will be required to monitor for Cryptosporidium if E. coli levels exceed 10 E. coli/100 mL for lakes and reservoir sources or 50 E. coli/100 mL for flowing stream sources. EPA estimated the percent of small plants that would be triggered into Cryptosporidium monitoring as being equal to the percent of large plants that would fall into any bin requiring additional treatment.

Estimates of laboratory fees, shipping costs, labor hours for sample collection, and hours for reporting results were used to predict PWS costs for initial source water monitoring under the LT2ESWTR. Table VI.D–4 summarizes the present value of monitoring costs for initial bin classification. Total present value monitoring costs for initial bin classification range from $45 million to $59 million depending on the occurrence data set and discount rate. Appendix D of the LT2ESWTR EA provides a full explanation of how these costs were developed (USEPA 2005a).

b. *Filtered PWSs treatment costs.* The Agency calculated treatment costs by estimating the number of plants that will add treatment technologies and coupling these estimates with unit costs ($/plant) of the selected technologies. Table VI.D–5 shows the number of plants estimated to select different treatment technologies; Table VI.D–6 summarizes the present value treatment costs and annualized present value costs for both filtered and unfiltered PWSs.

Table VI.D-4.– Summary of Present Value Monitoring Costs for Initial Bin Classification ($millions, 2003$)

System Size	ICR			ICRSSL			ICRSSM		
	Mean	Confidence Bounds		Mean	Confidence Bounds		Mean	Confidence Bounds	
		5th %ile	95th %ile		5th %ile	95th %ile		5th %ile	95th %ile
3 Percent									
< 10,000	$ 33.79	$ 32.11	$. 36.63	$ 25.24	$ 22.02	$ 27.44	$ 28.57	$ 26.36	$ 30.43
≥ 10,000	$ 25.22	$ 25.22	$ 25.22	$ 25.22	$ 25.22	$ 25.22	$ 25.22	$ 25.22	$ 25.22
Total	$ 59.01	$ 57.33	$ 61.86	$ 50.46	$ 47.24	$ 52.66	$ 53.79	$ 51.58	$ 55.66
7 Percent									
< 10,000	$ 29.05	$ 27.64	$ 31.45	$ 21.85	$ 19.13	$ 23.70	$ 24.65	$ 22.79	$ 26.22
≥ 10,000	$ 23.38	$ 23.38	$ 23.38	$ 23.38	$ 23.38	$ 23.38	$ 23.38	$ 23.38	$ 23.38
Total	$ 52.42	$ 51.01	$ 54.82	$ 45.22	$ 42.50	$ 47.07	$ 48.02	$ 46.17	$ 49.60

Source: Chapter 6 of the LT2ESWTR Economic Analysis (USEPA 2005a)

To estimate the number of filtered plants that would select a particular treatment technology, EPA followed a two step process. First, the number of plants that will be assigned to treatment bins requiring additional treatment was estimated. Second, the treatment technologies that plants will choose to meet these requirements was estimated using a "least-cost decision tree." In this estimate, EPA assumed that PWSs will select the least expensive technology or combination of technologies to meet the log removal requirements of a given treatment bin. Technology selections were constrained by maximum use percentages, which recognize that some plants will not be able to implement certain technologies because of site-specific conditions. In addition, certain potentially lower cost components of the microbial toolbox, such as changes to the plant intake, were not included because EPA lacked data to estimate the number of plants that could select it. These limitations on technology use may result in an overestimate of costs. An in-depth discussion of the technology selection methodology and unit cost estimates can be found in Appendices E and F of the LT2ESWTR EA (USEPA 2005a).

Table VI.D-5.– Filtered Plant Technology Selection Forecasts

Technology Selections[1]	Data Set[2]			Technology Selections[1]	Data Set[2]		
	ICR	ICRSSL	ICRSSM		ICR	ICRSSL	ICRSSM
Bag Filter 1.0 Log	1,523	1,219	1,421	Ozone 0.5 Log	27	21	25
Cartridge Filter 2.0 Log	209	20	58	Ozone 1.0 Log	18	14	16
Combined Filter Performance 0.5 Log	16	12	14	Ozone 2.0 Log	10	3	4
In-bank Filtration 1.0 Log	6	5	6	Secondary Filter 1.0 Log	0	0	0
MF/UF 2.5 Log	37	13	18	UV 2.5 Log	979	503	641
				WS Control 0.5 Log	0	0	0

[1]Some plants are projected to select more than one technology to meet LT2ESWTR bin requirements.
[2]Forecasts represent the median occurrence distribution.
Source: Chapter 6 of the *LT2ESWTR Economic Analysis* (USEPA 2005a)

c. *Unfiltered PWSs treatment costs.* The LT2ESWTR requires all unfiltered PWSs to achieve 2-log of inactivation if their mean source water Cryptosporidium concentration is less than or equal to 0.01 oocysts/L and 3-log of inactivation if it is greater than 0.01 oocysts/L. For most PWSs, UV appears to be the least expensive technology that can achieve these levels of Cryptosporidium inactivation, and EPA expects UV to be widely used by unfiltered PWSs to meet today's rule requirements. However, as with filtered PWSs, EPA estimated that a small percentage of plants would elect to install a technology more expensive than UV due to the configuration of

existing equipment or other factors. Ozone is the next least expensive technology that will meet the inactivation requirements for some PWSs and EPA estimated that it will be used by plants that do not use UV.

All unfiltered PWSs must meet requirements of the LT2ESWTR; therefore, 100 percent of unfiltered PWSs are estimated to add technology. This assumes that no unfiltered PWSs currently use these additional treatment technologies. For this cost analysis, EPA assumed that all very small unfiltered PWSs will use UV; for all other unfiltered PWS sizes, EPA estimated that 90 percent will install UV and 10 percent will add ozone. Treatment costs for unfiltered PWSs are included in Table VI.D–6.

Table VI.D-6.–Total Present Value and Annualized Present Value Treatment Costs for Filtered and Unfiltered Plants

	Capital - Present Value			O & M - Annualized			Total - Annualized		
	Mean	5th %ile	95th %ile	Mean	5th %ile	95th %ile	Mean	5th %ile	95th %ile
Dataset	A	B	C	D	E	F	G	H	I
3 percent									
ICR	$1,426.5	$1,128.4	$1,780.9	$ 33.7	$ 28.7	$ 39.6	$ 115.6	$ 93.5	$ 141.9
ICRSSL	$ 998.5	$ 723.2	$1,263.1	$ 18.8	$ 14.2	$ 22.6	$ 76.1	$ 55.7	$ 95.2
ICRSSM	$1,141.0	$ 875.4	$1,413.9	$ 23.2	$ 19.1	$ 27.2	$ 88.8	$ 69.4	$ 108.4
7 percent									
ICR	$1,157.1	$ 915.3	$1,444.3	$ 29.4	$ 25.0	$ 34.6	$ 128.7	$ 103.6	$ 158.5
ICRSSL	$ 812.2	$ 588.7	$1,027.0	$ 16.4	$ 12.4	$ 19.7	$ 86.1	$ 62.9	$ 107.9
ICRSSM	$ 927.1	$ 711.5	$1,148.7	$ 20.3	$ 16.7	$ 23.7	$ 99.8	$ 77.7	$ 122.3

Source: Chapter 6 of the LT2ESWTR Economic Analysis (USEPA 2005a)

d. *Uncovered finished water storage facilities.* As part of the LT2ESWTR, PWSs with uncovered finished water storage facilities must either cover the storage facility or treat the discharge to achieve inactivation and/or removal of at least 2-log Cryptosporidium, 3-log Giardia lamblia, and 4-log viruses. To develop national cost estimates for PWSs to comply with these provisions, unit costs for each compliance alternative and the percentage of PWSs selecting each alternative were estimated for the inventory of uncovered finished water storage facilities. From a recent survey of EPA Regions, EPA estimates that there are currently 81 uncovered finished water storage facilities for which PWSs must take steps to comply with the LT2ESWTR. A full description of the unit costs and other assumptions used in this analysis is presented in Chapter 6 and Appendix I of the LT2ESWTR EA (USEPA 2005a).

To comply with the treatment requirements, EPA determined that the least-cost treatment option is a combination of chlorine and UV. For PWSs with uncovered storage facility capacities of 5 million gallons (MG) or less, covering the storage facilities is the least expensive alternative. Although disinfection is the least expensive alternative for the remaining PWSs, the ability of a PWS to use booster chlorination depends on their current residual disinfectant type. Somewhat less than half of all surface water PWSs are predicted to use chloramination following implementation of the Stage 2 DBPR. Adding chlorine to water that has been treated with chloramines is not a feasible alternative; therefore, the fraction of PWSs projected to add UV and booster chlorination to the effluent from the uncovered storage facility was estimated at 50 percent, with the remaining 50 percent projected to add covers.

Table VI.D–7 summarizes total annualized present value costs for the uncovered finished water storage facility requirements using both 3 and 7 percent discount rates. EPA estimates the total annualized present value cost for covering or treating the water from uncovered finished water storage facilities to be approximately $10 million at a 3 percent discount rate and $13 million at a 7 percent discount rate.

Table VI.D-7.– Estimated Annualized Present Value Cost for Uncovered Finished Water Storage Facility Provision ($millions, 2003$)

System Size (Population Served)	Annualized Cost at 3%			Annualized Cost at 7%		
	Capital	O&M	Total	Capital	O&M	Total
<10,000	$ 0.01	$ 0.00	$ 0.01	$ 0.01	$ 0.00	$ 0.02
≥10,000	$ 6.52	$ 3.73	$ 10.24	$ 9.39	$ 3.68	$ 13.07
Total	$ 6.53	$ 3.73	$ 10.26	$ 9.40	$ 3.68	$ 13.08

Source: Appendix II of the *LT2ESWTR Economic Analysis* (USEPA 2005a)

e. *Future monitoring costs.* Six years after initial bin classification, filtered and unfiltered PWSs must conduct a second round of monitoring to assess whether source water Cryptosporidium levels have changed significantly. EPA will evaluate new analytical methods and surrogate indicators of microbial water quality in the interim. While the costs of monitoring are likely to change in the 9 years following rule promulgation, it is difficult to predict how they will change. In the absence of any other information, EPA assumed that the laboratory costs will be the same as for the initial monitoring.

All PWSs that conducted initial monitoring were assumed to conduct the second round of monitoring, except for those PWSs that installed treatment that achieves a total of 5.5-log or greater treatment for Cryptosporidium as a result of the rule. These PWSs are exempt from monitoring under the LT2ESWTR. EPA estimates that the cost of the second round of source water monitoring will range from $21 million to $36 million, depending on the occurrence data set and discount rate used in the estimate. Appendix D of the EA provides further details (USEPA 2005a).

f. Sensitivity analysis-influent bromide levels on technology selection for filtered plants. One concern with the ICR data set is that it may not reflect influent bromide levels in some PWSs during droughts. High influent bromide levels (the precursor for bromate formation) limits ozone use because some PWSs would not be able to meet the MCL for bromate. EPA conducted a sensitivity analysis to estimate the impact that higher influent bromide levels would have on technology decisions. The sensitivity analysis assumed influent bromide concentrations of 50 parts per billion (ppb) above the ICR concentrations. Results of the analysis indicate that this higher bromide level has a minimal impact on costs.

3. State/Primacy Agency Costs

EPA estimates that States (including primacy agencies) will incur an annualized present value cost of $1.1 to 1.2 million using a 3 percent discount rate and $1.4 million at 7 percent. State implementation activities include regulation adoption, program implementation, training State staff, training PWS staff, providing technical assistance to PWSs, and updating management systems. To estimate implementation costs to States, the number of full-time employees (FTEs) per activity is multiplied by the number of labor hours per FTE, the cost per labor hour, and the number of States and Territories.

In addition to implementation costs, States will also incur costs associated with managing monitoring data. Because EPA will directly manage reporting, approval, and analysis of results from the initial round of monitoring by large PWSs (serving at least 10,000 people), States are not predicted to incur costs for these activities. States will, however, incur costs associated with small PWS monitoring. This is a result of the later start of small PWS monitoring, which will mean that some States will assume primacy for small PWS monitoring. In addition, States will review the second round of monitoring results. States will also incur costs for reviewing technology compliance data and consulting with PWSs regarding disinfection benchmarking (for PWSs that change their disinfection procedures to comply with today's rule). Appendix D of the LT2ESWTR EA provides more information about the State cost analysis (USEPA 2005a).

4. Non-Quantified Costs

EPA has quantified all the major costs for this rule and has provided uncertainty analyses to bound the over or underestimates in the costs. There are some costs that EPA has not quantified, however, because of lack of data. For example, some PWSs may merge with neighboring PWSs to comply with this rule. Such changes have both costs (legal fees and connecting infrastructure) and benefits (economies of scale). Likewise, PWSs would incur costs for procuring a new source of water that may result in lower overall treatment costs.

In addition, the Agency was unable to predict the usage or estimate the costs of several options in the microbial toolbox. These options include intake management and demonstrations of performance. They have not been included in the quantified analysis because data are not available to estimate the number of PWSs that may use these toolbox options to comply with the LT2ESWTR. Not including these generally lower-cost options may result in overestimation of costs.

E. What Are the Household Costs of the LT2ESWTR?

Another way to assess a rule's impact is to consider how it may impact residential water bills. This analysis considers the potential increase in a household's water bill if a CWS passed the entire cost increase resulting from this rule on to its customers. This serves as a tool to gauge potential impacts and should not be construed as precise estimates of potential changes to individual water bills.

Included in this analysis are all PWS costs, including rule implementation, initial and future monitoring for bin classification, additional Cryptosporidium treatment, and treating

or covering uncovered finished water storage facilities. Costs for Cryptosporidium monitoring by small PWSs, additional Cryptosporidium treatment, and uncovered finished water storage facilities are assigned only to the subset of PWSs expected to incur them. Although implementation and monitoring represent relatively small, one-time costs, they have been included in the analysis to provide a complete distribution of the potential household cost. A detailed description of the derivation of household costs is in Chapter 6 and Appendix J of the LT2ESTWR EA (USEPA 2005a).

For PWSs that purchase treated water (i.e., purchased PWSs) from larger nonpurchased PWSs, the households costs are calculated based on the unit treatment costs of the larger PWS but included in the distribution for the size category of the purchased PWS. Households costs for these purchased PWSs are based on the household usage rates appropriate for the retail PWS and not the PWS selling (wholesaling) the water. This approach for purchased PWSs reflects the fact that although they will not face increased costs from adding their own treatment, whatever costs the wholesale PWS incurs will likely be passed on as higher water costs.

Table VI.E–1 shows the results of the household cost analysis. In addition to mean and median estimates, EPA calculated the 90th and the 95th percentiles. EPA estimates that all households served by surface and GWUDI sources will face some increase in household costs due to implementation of the LT2ESWTR. Of all the households subject to the rule, from 22 to 41 percent are projected to incur costs for adding treatment, depending on the Cryptosporidium occurrence data set used.

Approximately 92 percent of the households potentially subject to the rule are served by PWSs serving at least 10,000 people and 99.8 percent are served by PWSs serving at least 500 people; these PWSs experience the lowest increases in costs due to significant economies of scale. Over 95 percent of all households are estimated to face an annual cost increase of less than $12. Households served by small PWSs that install advanced technologies will face the greatest increases in annual costs. EPA expects that the model's projections for these PWSs are, in some cases, overstated. Some PWSs are likely to find alternative treatment techniques such as other toolbox options not included in this analysis, or sources of water (ground water, purchased water, or consolidating with another PWS) that would be less costly than installing more expensive treatment technologies.

Table VI.E-1.– Potential Annual Household Costs Impacts for the Preferred Regulatory Option (2003$)

System Type/Size	Households	Mean	Median	90th Percentile	95th Percentile	Percent of Systems with Household Cost Increase < $12	Percent of Systems with Household Cost Increase < $120
ICR							
All CWS	68,857,992	$2.59	$0.21	$6.43	$9.97	96.49%	99.99%
CWS ≤ 10,000	5,587,602	$4.14	$0.56	$9.97	$14.79	91.19%	99.88%
CWS < 500	158,900	$13.09	$3.86	$28.66	$53.60	63.20%	98.87%
ICRSSL							
All CWS	68,857,992	$1.67	$0.09	$6.37	$6.42	97.96%	100.00%
CWS ≤ 10,000	5,587,602	$2.49	$0.36	$6.60	$9.37	96.46%	99.94%
CWS < 500	158,900	$8.58	$2.91	$17.44	$29.01	72.61%	99.50%
ICRSSM							
All CWS	68,857,992	$1.97	$0.09	$6.37	$6.85	97.47%	99.99%
CWS ≤ 10,000	5,587,602	$3.00	$0.49	$7.02	$11.39	95.19%	99.93%
CWS < 500	158,900	$10.10	$2.90	$26.24	$35.97	68.73%	99.31%
ICR - High							
All CWS	68,857,992	$2.84	$0.21	$6.43	$9.97	96.09%	99.99%
CWS ≤ 10,000	5,587,602	$4.58	$0.61	$11.50	$15.30	90.22%	99.86%
CWS < 500	158,900	$7.21	$2.91	$16.81	$26.25	75.79%	99.80%
ICRSSL - Low							
All CWS	68,857,992	$1.42	$0.03	$5.65	$6.42	98.37%	100.00%
CWS ≤ 10,000	5,587,602	$2.06	$0.23	$6.58	$7.47	97.21%	99.96%
CWS < 500	158,900	$14.42	$4.79	$30.00	$54.42	62.07%	98.58%

Source: Chapter 6 of the *LT2ESWTR Economic Analysis* (USEPA 2005a)

F. What Are the Incremental Costs and Benefits of the LT2ESWTR?

Incremental costs and benefits are those that are incurred or realized in reducing Cryptosporidium exposures from one regulatory alternative to the next. Estimates of incremental costs and benefits are useful in considering the economic efficiency of different regulatory alternatives evaluated by EPA. Generally, the goal of an incremental analysis is to identify the most efficient regulatory alternative. However, this analysis is incomplete because some benefits from this rule are unquantified and not monetized. Incremental analyses should consider both quantified and unquantified (where possible) benefits and costs.

Usually an incremental analysis implies increasing levels of stringency along a single parameter, with each alternative providing all the protection of the previous alternative, plus additional protection. However, the regulatory alternatives evaluated for the LT2ESWTR vary by multiple parameters (e.g., treatment bin boundaries, treatment requirements). The comparison between any two alternatives is, therefore, between two separate sets of benefits, in the sense that they may be distributed to somewhat different population groups.

The regulatory alternatives, however, do achieve increasing levels of benefits at increasing levels of costs. As a result, displaying incremental net benefits from the baseline and alternative to alternative is possible. Tables VI.F–1a and VI.F–1b show incremental costs, benefits, and net benefits for the four regulatory alternatives, A1–A4, shown in Table VI.A–1, using the enhanced and traditional COI, respectively. All values are annualized present values expressed in Year 2003 dollars. The displayed values are the mean estimates for each occurrence distribution and infectivity model.

With the enhanced COI, incremental costs are generally closest to incremental benefits for A2, a more stringent alternative than A3, which is today's final rule. For the traditional COI, incremental costs most closely equal incremental benefits for A3 under the majority of conditions evaluated.

G. Are There Benefits From the Reduction of Co-Occurring Contaminants?

While the quantified and monetized benefits for the LT2ESWTR includes only reductions in illness and mortality attributable to Cryptosporidium, today's rule will reduce exposure to and disease from other microbial pathogens and, in some cases, chemical contaminants.

Table VI.F-1a.– Incremental Net Benefits by Rule Alternative—Enhanced COI (Annualized Present Value, $millions, 2003$)*

Data Set	Rule Alternative	Annual Costs	Annual Benefits			Incremental Costs	Incremental Benefits			Incremental Net Benefits		
			Low	Medium	High		Low	Medium	High	Low	Medium	High
		A	B			C	D			E=D-C		
3 Percent Discount Rate												
ICR	A4	$ 81	$ 645	$ 1,753	$ 2,661	$ 81	$ 645	$ 1,753	$ 2,661	$ 565	$ 1,673	$ 2,580
	A3 - Preferred	$ 133	$ 687	$ 1,853	$ 2,822	$ 53	$ 42	$ 100	$ 161	$ (11)	$ 47	$ 108
	A2	$ 163	$ 695	$ 1,871	$ 2,851	$ 30	$ 7	$ 18	$ 29	$ (23)	$ (12)	$ (1)
	A1	$ 403	$ 705	$ 1,895	$ 2,891	$ 239	$ 10	$ 24	$ 40	$ (229)	$ (216)	$ (200)
ICRSSL	A4	$ 57	$ 155	$ 405	$ 657	$ 57	$ 155	$ 405	$ 657	$ 98	$ 347	$ 600
	A3 - Preferred	$ 93	$ 177	$ 458	$ 744	$ 35	$ 22	$ 53	$ 87	$ (13)	$ 18	$ 52
	A2	$ 123	$ 191	$ 489	$ 795	$ 30	$ 13	$ 31	$ 51	$ (17)	$ 1	$ 21
	A1	$ 403	$ 221	$ 558	$ 910	$ 280	$ 31	$ 69	$ 115	$ (249)	$ (210)	$ (165)
ICRSSM	A4	$ 65	$ 306	$ 796	$ 1,247	$ 65	$ 306	$ 796	$ 1,247	$ 241	$ 731	$ 1,182
	A3 - Preferred	$ 106	$ 344	$ 886	$ 1,393	$ 41	$ 38	$ 90	$ 146	$ (3)	$ 49	$ 105
	A2	$ 137	$ 359	$ 919	$ 1,447	$ 31	$ 15	$ 33	$ 54	$ (16)	$ 2	$ 23
	A1	$ 403	$ 386	$ 981	$ 1,548	$ 266	$ 27	$ 62	$ 102	$ (239)	$ (204)	$ (164)
7 Percent Discount Rate												
ICR	A4	$ 93	$ 523	$ 1,421	$ 2,156	$ 93	$ 523	$ 1,421	$ 2,156	$ 430	$ 1,328	$ 2,063
	A3 - Preferred	$ 150	$ 556	$ 1,501	$ 2,286	$ 57	$ 34	$ 80	$ 130	$ (24)	$ 23	$ 72
	A2	$ 182	$ 562	$ 1,515	$ 2,309	$ 31	$ 6	$ 14	$ 23	$ (26)	$ (17)	$ (8)
	A1	$ 436	$ 570	$ 1,534	$ 2,341	$ 255	$ 8	$ 19	$ 32	$ (246)	$ (236)	$ (223)
ICRSSL	A4	$ 68	$ 126	$ 328	$ 533	$ 68	$ 126	$ 328	$ 533	$ 58	$ 261	$ 465
	A3 - Preferred	$ 107	$ 144	$ 371	$ 603	$ 39	$ 18	$ 43	$ 70	$ (21)	$ 4	$ 31
	A2	$ 139	$ 154	$ 396	$ 644	$ 32	$ 11	$ 25	$ 41	$ (21)	$ (7)	$ 9
	A1	$ 437	$ 221	$ 452	$ 737	$ 298	$ 67	$ 56	$ 92	$ (231)	$ (242)	$ (205)
ICRSSM	A4	$ 76	$ 248	$ 645	$ 1,011	$ 76	$ 248	$ 645	$ 1,011	$ 172	$ 569	$ 935
	A3 - Preferred	$ 121	$ 279	$ 718	$ 1,128	$ 45	$ 31	$ 73	$ 118	$ (14)	$ 27	$ 72
	A2	$ 154	$ 291	$ 744	$ 1,171	$ 33	$ 12	$ 27	$ 43	$ (21)	$ (6)	$ 10
	A1	$ 437	$ 313	$ 794	$ 1,253	$ 283	$ 22	$ 50	$ 82	$ (261)	$ (233)	$ (201)

Table VI.F-1b.– Incremental Net Benefits by Rule Alternative—Traditional COI (Annualized Present Value, $millions, 2003$)*

Data Set	Rule Alternative	Annual Costs	Annual Benefits			Incremental Costs	Incremental Benefits			Incremental Net Benefits		
			Low	Medium	High		Low	Medium	High	Low	Medium	High
		A	B			C	D			E=D-C		
3 Percent Discount Rate												
ICR	A4	$ 81	$ 468	$ 1,273	$ 1,937	$ 81	$ 468	$ 1,273	$ 1,937	$ 388	$ 1,193	$ 1,856
	A3 - Preferred	$ 133	$ 497	$ 1,341	$ 2,047	$ 53	$ 29	$ 68	$ 110	$ (24)	$ 15	$ 57
	A2	$ 163	$ 502	$ 1,353	$ 2,066	$ 30	$ 5	$ 12	$ 20	$ (25)	$ (18)	$ (10)
	A1	$ 403	$ 509	$ 1,369	$ 2,093	$ 239	$ 7	$ 16	$ 27	$ (232)	$ (223)	$ (212)
ICRSSL	A4	$ 57	$ 115	$ 299	$ 486	$ 57	$ 115	$ 299	$ 486	$ 57	$ 242	$ 429
	A3 - Preferred	$ 93	$ 130	$ 335	$ 546	$ 35	$ 15	$ 36	$ 59	$ (20)	$ 1	$ 24
	A2	$ 123	$ 139	$ 356	$ 580	$ 30	$ 9	$ 21	$ 35	$ (21)	$ (9)	$ 4
	A1	$ 403	$ 160	$ 403	$ 658	$ 280	$ 21	$ 47	$ 78	$ (259)	$ (233)	$ (201)
ICRSSM	A4	$ 65	$ 224	$ 583	$ 915	$ 65	$ 224	$ 583	$ 915	$ 159	$ 518	$ 851
	A3 - Preferred	$ 106	$ 250	$ 644	$ 1,014	$ 41	$ 26	$ 61	$ 99	$ (15)	$ 20	$ 58
	A2	$ 137	$ 260	$ 666	$ 1,051	$ 31	$ 10	$ 23	$ 37	$ (21)	$ (9)	$ 6
	A1	$ 403	$ 279	$ 708	$ 1,120	$ 266	$ 18	$ 42	$ 69	$ (247)	$ (224)	$ (197)
7 Percent Discount Rate												
ICR	A4	$ 93	$ 380	$ 1,034	$ 1,574	$ 93	$ 380	$ 1,034	$ 1,574	$ 287	$ 941	$ 1,481
	A3 - Preferred	$ 150	$ 403	$ 1,089	$ 1,662	$ 57	$ 23	$ 55	$ 88	$ (34)	$ (3)	$ 31
	A2	$ 182	$ 407	$ 1,099	$ 1,678	$ 31	$ 4	$ 10	$ 16	$ (28)	$ (22)	$ (15)
	A1	$ 436	$ 413	$ 1,112	$ 1,700	$ 255	$ 6	$ 13	$ 22	$ (249)	$ (242)	$ (233)
ICRSSL	A4	$ 68	$ 93	$ 243	$ 396	$ 68	$ 93	$ 243	$ 396	$ 26	$ 175	$ 328
	A3 - Preferred	$ 107	$ 105	$ 272	$ 443	$ 39	$ 12	$ 29	$ 48	$ (27)	$ (10)	$ 9
	A2	$ 139	$ 113	$ 289	$ 471	$ 32	$ 7	$ 17	$ 28	$ (25)	$ (15)	$ (4)
	A1	$ 437	$ 130	$ 327	$ 534	$ 298	$ 17	$ 38	$ 63	$ (281)	$ (260)	$ (235)
ICRSSM	A4	$ 76	$ 182	$ 474	$ 744	$ 76	$ 182	$ 474	$ 744	$ 106	$ 398	$ 668
	A3 - Preferred	$ 121	$ 203	$ 523	$ 824	$ 45	$ 21	$ 49	$ 80	$ (24)	$ 4	$ 35
	A2	$ 154	$ 211	$ 541	$ 853	$ 33	$ 8	$ 18	$ 29	$ (25)	$ (15)	$ (3)
	A1	$ 437	$ 226	$ 575	$ 909	$ 283	$ 15	$ 34	$ 56	$ (268)	$ (249)	$ (227)

*Notes: The traditional COI only includes valuation for medical costs and lost work time (including some portion of unpaid household production). The enhanced COI also factors in valuations for lost personal time (non-worktime) such as child care and homemaking (to the extent not covered by the traditional COI), time with family, and recreation, and lost productivity at work on days when workers are ill but go to work anyway. Source: Chapter 8 of the *LT2ESWTR Economic Analysis* (USEPA 2005a)
High, medium, and low estimates reflect the mean estimates for a range of dose-response modeling assumptions. See Appendix N of the LT2ESWTR Economic Analysis.

All of the options in the microbial toolbox that PWSs will implement to comply with today's rule will also reduce levels of other microbial pathogens. For example, watershed control programs and intake relocation

will cut overall pathogen levels by reducing fecal contamination in the source water. Membrane, bag, and cartridge filters will remove pathogenic protozoa like Giardia lamblia that are similar in size to or larger than Cryptosporidium. Lowering finished water turbidity from conventional and direct filtration will improve removal of pathogens across a broad size range, including viruses, bacteria, and protozoa. Inactivation technologies like ozone and UV are highly effective against a large number of different pathogen types.

Some membrane technologies that PWSs may install to comply with the LT2ESWTR can also reduce or eliminate chemical contaminants including arsenic, DBPs, and atrazine. The use of UV for inactivation of Cryptosporidium may reduce the chlorine dosage that some PWSs must apply, which can reduce levels of DBPs. EPA has recently finalized a rule to further control arsenic levels in drinking water and is concurrently establishing the Stage 2 DBPR to address DBP control.

The extent to which the LT2ESWTR can reduce the overall risk from other contaminants has not been quantitatively evaluated because EPA lacks sufficient data on the co-occurrence among Cryptosporidium and other microbial pathogens and contaminants. Further, due to the difficulties in establishing which PWSs would have multiple problems, such as microbial contamination, arsenic, and DBPs or any combination of the three, no estimate was made of the potential cost savings from addressing more than one contaminant simultaneously.

H. Are There Increased Risks From Other Contaminants?

It is unlikely that the LT2ESWTR will result in a significant increase in risk from other contaminants for most PWSs. Many of the options that PWSs will select to comply with the LT2ESWTR, such as UV, additional or improved filtration, and watershed control, do not form DBPs. Ozone, another technology that is effective against Cryptosporidium, does form DBPs (e.g., bromate). However, bromate is currently regulated under the Stage 1 DBPR, and PWSs will have to comply with this regulation if they implement ozone to meet the LT2ESWTR.

I. What Are the Effects of the Contaminant on the General Population and Groups Within the General Populations That Are Identified as Likely To be at Greater Risk of Adverse Health Effects?

Section III of this preamble discusses the health effects associated with Cryptosporidium on the general population as well as the effects on other sensitive sub-populations. In addition, health effects associated with children and pregnant women are discussed in greater detail in section VII.G of this preamble.

J. What Are the Uncertainties in the Risk, Benefit, and Cost Estimates for the LT2ESWTR?

For today's final rule, EPA has modeled the current baseline risk from Cryptosporidium exposure through drinking water, along with the reduction in risk and the cost for various rule alternatives. There is uncertainty in the risk calculation, the benefit estimates, the cost estimates, and the interaction with other regulations. The LT2ESWTR EA has an extensive discussion of relevant uncertainties (USEPA 2005a), and a brief summary of the major uncertainties follows.

In regard to the risk estimates, the most significant areas of uncertainty are Cryptosporidium occurrence, treatment, and infectivity. Among the three available occurrence data sets, the ICR plant-mean data were higher than the ICRSSM or ICRSSL plant-mean data at the 90th percentile. The reasons for these differing results are not well understood but may stem from year-to-year variation in occurrence and differences in the sampling and measurement methods employed. The ICRSSM and ICRSSL data sets use a newer, more reliable sampling method but include fewer plants and a shorter time frame. Additional uncertainty is associated with estimating finished water occurrence because the analysis is based on estimates of treatment plant performance in removing Cryptosporidium.

EPA has addressed some of the uncertainty in occurrence by evaluating benefits and costs for regulatory alternatives with each Cryptosporidium data set. Further, in the 2-dimensional Monte Carlo simulation models used to estimate risk, key parameters like occurrence and treatment efficiency are treated as both variable and uncertain. This approach is intended to account for the limitations in available data and the recognized variability in these parameters among PWSs.

EPA has also considered occurrence data from additional sources. For example, the LT2ESWTR EA discusses a study of infectious Cryptosporidium in the finished water of 82 filtration plants by Aboytes et.al, 2004. The mean level of infectious Cryptosporidium measured in this study is higher than EPA has estimated using the ICR, ICRSSM, or ICRSSL data sets. This result suggests that Cryptosporidium occurrence at these plants may have exceeded levels during the ICR and ICRSS surveys or that EPA may have overestimated the efficiency of treatment plants in removing Cryptosporidium.

In regard to Cryptosporidium infectivity, EPA evaluated data from human feeding studies conducted with different Cryptosporidium isolates. The measured infectivity of these isolates varied widely, however, and how well these isolates represent Cryptosporidium that causes disease in PWSs is uncertain. In addition, extrapolating from the higher Cryptosporidium dosing levels used in the human feeding studies to the exposure levels typical for drinking water (e.g., one oocyst) is uncertain. Another source of uncertainty is differences that exist among populations groups, such as individuals that are more sensitive (e.g., children, immunocompromised) or less sensitive (previously infected adults).

EPA accounted for some of this uncertainty in infectivity by treating the human feeding study results for different Cryptosporidium isolates as random samples from a larger and unknown environmental distribution of Cryptosporidium infectivity. EPA used a variety of models for this analysis, as recommended by the SAB, and presents results for a range of models to account for uncertainty in model selection. In addition, limited data on levels of Cryptosporidium in the 1993 Milwaukee outbreak and associated disease incidence suggest that the infectivity of the Cryptosporidium responsible for that outbreak is within the range EPA has estimated for the risk assessment in today's rule.

Unquantified benefits from the reduction of co-occurring microbial pathogens, as described earlier, are a significant source of uncertainty in the estimate of benefits for the LT2ESWTR. EPA is also uncertain about the monetization of avoided disease from Cryptosporidium and has addressed this uncertainty through the use of both traditional and enhanced COI values for benefits estimates.

While all of the significant costs of today's rule have been identified by

EPA, there are uncertainties in the estimates. Occurrence is the most significant source of uncertainty in costs, and EPA has attempted to account for this uncertainty through the use of different occurrence data sets and Monte Carlo modeling as described previously. EPA has also estimated uncertainty in unit process costs for treatment technologies. In addition, the cost assessment for today's rule includes sensitivity analyses, such an assessment of the impact of influent bromide levels on technology selection. Chapter 6 of the LT2ESWTR EA provides a fuller description of uncertainties in the cost estimates (USEPA 2005a).

Last, EPA has recently finalized or is currently finalizing new regulations for arsenic, radon, Cryptosporidium in small surface water PWSs, filter backwash recycling, microbial pathogens in PWSs using ground water, and DBPs. These rules may have overlapping impacts on some PWSs, but the extent is not possible to estimate due to lack of information on co-occurrence. However, PWSs may choose treatment technologies that will address multiple contaminants. Therefore, while the total cost impact of these drinking water rules is uncertain, it is most likely less than the estimated total cost of all individual rules combined.

K. What Is the Benefit/Cost Determination for the LT2ESWTR?

The Agency has determined that the benefits of the LT2ESWTR justify the costs. As discussed in section VII.C, the rule provides a large reduction in endemic cryptosporidiosis illness and mortalities. More stringent alternatives provide greater reductions but at higher costs. Alternative A1 provides the greatest overall reduction in illnesses and mortalities but the incremental benefits between this option and alternative A3 (today's final rule) are relatively small while the incremental costs are significant. In addition, today's rule, unlike alternative A1, specifically targets those PWSs whose source water requires higher levels of treatment.

Tables VI.K–1a and VI.K–1b present net benefits for the four regulatory alternatives that were evaluated. Generally, analysis of net benefits is used to identify alternatives where benefits exceed costs, as well as the alternative that maximizes net benefits. However, as with the analysis of incremental net benefits discussed previously, the usefulness of this analysis in evaluating regulatory alternatives for the LT2ESWTR is somewhat limited because many benefits from this rule are unquantified and nonmonetized. Analyses of net benefits should consider both quantified and unquantified (where possible) benefits and costs.

Also, as noted earlier, the regulatory alternatives considered for the LT2ESWTR vary both in the population that experiences benefits and costs (i.e., treatment bin boundaries) and the magnitude of the benefits and costs (i.e., treatment requirements). Consequently, the more stringent regulatory alternatives provide benefits to population groups that do not experience any benefit under less stringent alternatives.

As shown by Tables VI.K–1a and VI.K–1b, net benefits are positive for all four regulatory alternatives evaluated under most occurrence and discount rate scenarios. With both the enhanced COI and traditional COI, net benefits are highest for the alternative A3, which is today's final rule, under the majority of occurrence distributions and discount rates evaluated.

Table VI.K-1a.–Mean Net Benefits by Rule Option—Enhanced COI[1] ($millions, 2003$)

Data Set	Rule Alternative	Annualized Value					
		3%, 25 Years			7%, 25 Years		
		Low	Medium	High	Low	Medium	High
ICR	A1	$ 260	$ 1,492	$ 2,447	$ 126	$ 1,098	$ 1,897
	A2	$ 498	$ 1,708	$ 2,655	$ 366	$ 1,333	$ 2,112
	A3 - Preferred	$ 527	$ 1,720	$ 2,662	$ 396	$ 1,351	$ 2,126
	A4	$ 550	$ 1,673	$ 2,566	$ 427	$ 1,328	$ 2,061
ICRSSL	A1	$ (223)	$ 156	$ 466	$ (265)	$ 15	$ 292
	A2	$ 43	$ 366	$ 647	$ 6	$ 257	$ 496
	A3 - Preferred	$ 65	$ 365	$ 632	$ 32	$ 264	$ 491
	A4	$ 87	$ 347	$ 589	$ 58	$ 261	$ 465
ICRSSM	A1	$ (58)	$ 578	$ 1,104	$ (132)	$ 358	$ 809
	A2	$ 198	$ 782	$ 1,285	$ 130	$ 591	$ 1,010
	A3 - Preferred	$ 218	$ 780	$ 1,267	$ 153	$ 597	$ 1,002
	A4	$ 230	$ 731	$ 1,171	$ 172	$ 569	$ 935

Table VI.K-1b.–Mean Net Benefits by Rule Option—Traditional COI[1] ($millions, 2003$)

Data Set	Rule Alternative	Annualized Value					
		3%, 25 Years			7%, 25 Years		
		Low	Medium	High	Low	Medium	High
ICR	A1	$ 64	$ 967	$ 1,649	$ (31)	$ 675	$ 1,256
	A2	$ 305	$ 1,190	$ 1,870	$ 211	$ 917	$ 1,481
	A3 - Preferred	$ 337	$ 1,208	$ 1,887	$ 243	$ 939	$ 1,502
	A4	$ 373	$ 1,193	$ 1,842	$ 285	$ 941	$ 1,478
ICRSSL	A1	$ (284)	$ 0	$ 214	$ (315)	$ (109)	$ 90
	A2	$ (9)	$ 233	$ 432	$ (35)	$ 150	$ 324
	A3 - Preferred	$ 18	$ 242	$ 433	$ (7)	$ 166	$ 331
	A4	$ 46	$ 242	$ 418	$ 25	$ 175	$ 327
ICRSSM	A1	$ (165)	$ 306	$ 676	$ (218)	$ 138	$ 465
	A2	$ 99	$ 529	$ 890	$ 50	$ 387	$ 692
	A3 - Preferred	$ 124	$ 538	$ 889	$ 77	$ 402	$ 698
	A4	$ 148	$ 518	$ 840	$ 106	$ 398	$ 668

[1]The traditional COI only includes valuation for medical costs and lost work time (including some portion of unpaid household production). The enhanced COI also factors in valuations for lost personal time (non-worktime) such as child care and homemaking (to the extent not covered by the traditional COI), time with family, and recreation, and lost productivity at work on days when workers are ill but go to work anyway. Source: Chapter 8 of the *LT2ESWTR Economic Analysis* (USEPA 2005a) High, medium, and low estimates reflect the mean estimates for a range of dose-response modeling assumptions. See Appendix N of the LT2ESWTR Economic Analysis.

In addition to the net benefits of the LT2ESWTR, the Agency used several other techniques to compare costs and benefits. For example, EPA calculated the cost of the rule per case avoided. Tables VI.K–2a, b and c show both the cost of the rule per illness avoided and cost of the rule per death avoided. This cost effectiveness measure is another way of examining the benefits and costs of the rule but should not be used to compare alternatives because an alternative with the lowest cost per illness/death avoided may not result in the highest net benefits. With the exception of alternative A1, the rule options look favorable when the cost per case avoided is compared to both the weighted cost of cryptosporidiosis illness ($844 and $274 for the two COI approaches) and the mean value of a statistical death avoided—approximately $7 million dollars. Additional information about this analysis and other methods of comparing benefits and costs can be found in chapter 8 of the LT2ESWTR EA (USEPA 2005a).

Table VI.K-2a.–Cost per Illness or Death Avoided[1], Low Estimate

Data Set	Rule Alternative	Cost Per Illness Avoided ($)		Cost Per Death Avoided ($Millions, 2000$)		Benefit/Cost Ratio (Enhanced COI)		Benefit/Cost Ratio (Traditional COI)	
		3%	7%	3%	7%	3%	7%	3%	7%
ICR	A4	$ 398	$ 837	$ 1.8	$ 3.9	8.0	5.6	5.8	4.1
	A3 - Preferred	$ 566	$ 1,172	$ 2.7	$ 5.6	5.2	3.7	3.7	2.7
	A2	$ 739	$ 1,503	$ 3.5	$ 7.1	4.3	3.1	3.1	2.2
	A1	$ 1,791	$ 3,546	$ 8.5	$ 16.7	1.8	1.3	1.3	0.9
ICRSSL	A4	$ 1,241	$ 2,666	$ 5.3	$ 11.3	2.7	1.9	2.0	1.4
	A3 - Preferred	$ 1,598	$ 3,366	$ 7.2	$ 15.1	1.9	1.3	1.4	1.0
	A2	$ 2,073	$ 4,265	$ 9.4	$ 19.4	1.5	1.1	1.1	0.8
	A1	$ 5,683	$ 11,259	$ 27.0	$ 53.3	0.6	0.5	0.4	0.3
ICRSSM	A4	$ 690	$ 1,470	$ 3.1	$ 6.5	4.7	3.3	3.5	2.4
	A3 - Preferred	$ 913	$ 1,913	$ 4.2	$ 8.9	3.2	2.3	2.4	1.7
	A2	$ 1,207	$ 2,474	$ 5.6	$ 11.5	2.6	1.9	1.9	1.4
	A1	$ 3,259	$ 6,456	$ 15.4	$ 30.6	1.0	0.7	0.7	0.5

Table VI.K-2b.–Cost per Illness or Death Avoided[1], Medium Estimate

Data Set	Rule Alternative	Cost Per Illness Avoided ($)		Cost Per Death Avoided ($Millions, 2000$)		Benefit/Cost Ratio (Enhanced COI)		Benefit/Cost Ratio (Traditional COI)	
		3%	7%	3%	7%	3%	7%	3%	7%
ICR	A4	$ 147	$ 309	$ 0.7	$ 1.4	21.7	15.3	15.8	11.1
	A3 - Preferred	$ 227	$ 468	$ 1.1	$ 2.2	13.9	10.0	10.1	7.2
	A2	$ 275	$ 559	$ 1.3	$ 2.6	11.5	8.3	8.3	6.0
	A1	$ 668	$ 1,322	$ 3.1	$ 6.2	4.7	3.5	3.4	2.5
ICRSSL	A4	$ 476	$ 1,022	$ 2.0	$ 4.3	7.1	4.9	5.2	3.6
	A3 - Preferred	$ 661	$ 1,385	$ 2.9	$ 6.1	4.9	3.5	3.6	2.6
	A2	$ 808	$ 1,663	$ 3.7	$ 7.5	4.0	2.9	2.9	2.1
	A1	$ 2,258	$ 4,472	$ 10.6	$ 21.0	1.4	1.0	1.0	0.7
ICRSSM	A4	$ 265	$ 565	$ 1.2	$ 2.5	12.3	8.5	9.0	6.3
	A3 - Preferred	$ 382	$ 796	$ 1.7	$ 3.6	8.4	5.9	6.1	4.3
	A2	$ 473	$ 969	$ 2.2	$ 4.5	6.7	4.8	4.9	3.5
	A1	$ 1,287	$ 2,548	$ 6.0	$ 11.9	2.4	1.8	1.8	1.3

Table VI.K-2c.–Cost per Illness or Death Avoided[1], High Estimate

Data Set	Rule Alternative	Cost Per Illness Avoided ($)		Cost Per Death Avoided ($Millions, 2000$)		Benefit/Cost Ratio (Enhanced COI)		Benefit/Cost Ratio (Traditional COI)	
		3%	7%	3%	7%	3%	7%	3%	7%
ICR	A4	$ 97	$ 205	$ 0.4	$ 0.9	33.0	23.2	24.0	16.9
	A3 - Preferred	$ 140	$ 289	$ 0.7	$ 1.4	21.2	15.2	15.3	11.0
	A2	$ 182	$ 369	$ 0.8	$ 1.7	17.5	12.7	12.7	9.2
	A1	$ 440	$ 872	$ 2.1	$ 4.1	7.2	5.4	5.2	3.9
ICRSSL	A4	$ 295	$ 633	$ 1.3	$ 2.7	11.4	7.9	8.5	5.8
	A3 - Preferred	$ 385	$ 810	$ 1.7	$ 3.6	8.0	5.6	5.9	4.2
	A2	$ 500	$ 1,029	$ 2.3	$ 4.6	6.5	4.6	4.7	3.4
	A1	$ 1,394	$ 2,762	$ 6.6	$ 13.0	2.3	1.7	1.6	1.2
ICRSSM	A4	$ 170	$ 363	$ 0.8	$ 1.6	19.3	13.4	14.2	9.9
	A3 - Preferred	$ 228	$ 478	$ 1.1	$ 2.2	13.1	9.3	9.6	6.8
	A2	$ 302	$ 619	$ 1.4	$ 2.9	10.6	7.6	7.7	5.5
	A1	$ 820	$ 1,624	$ 3.9	$ 7.6	3.8	2.9	2.8	2.1

[1]The calculations presented here do not reflect discounting of the physical incidence of morbidity or mortality.
Source: Chapter 8 of the *LT2ESWTR Economic Analysis* (USEPA 2005a)
Note: High, medium, and low estimates reflect the mean estimates for a range of dose-response modeling assumptions. See Appendix N of the LT2ESWTR Economic Analysis (USEPA, 2005a).

L. Summary of Major Comments

EPA received significant public comment on the analysis of benefits and costs of the August 11, 2003 proposed LT2ESWTR in the following areas: Cryptosporidium occurrence, drinking water consumption, Cryptosporidium infectivity (i.e., dose-response), and valuation of benefits. The following discussion summarizes public comment in these areas and EPA's responses.

1. Cryptosporidium Occurrence

With respect to the analysis of Cryptosporidium occurrence, two areas that received significant public comment are the quality of the ICR and ICRSS data sets (i.e., whether the estimates derived from them should be regarded as equally plausible) and the treatment of samples in which no Cryptosporidium is detected (i.e., observed zeros).

a. *Quality of the ICR and ICRSS data sets.* As noted earlier, the ICR, ICRSSM, and ICRSSL data sets differ significantly in the high concentration portion of the occurrence distribution (e.g., 90th percentile). While the measurement method employed in the ICRSS had higher recovery and less variable volumes assayed, the ICR produced a much greater number of assays and source waters sampled. Lacking a technical basis to conclude that one data set provides a better estimate, EPA conducted separate analyses of costs and benefits for all three data sets. EPA requested comment on this approach.

The majority of commenters on this issue supported EPA's approach of analyzing the three data sets separately to represent uncertainty about occurrence. Two commenters suggested that the ICR data would be more reliable for estimating national occurrence due to the larger number of samples, while two others viewed the ICRSS data as more reliable due to the improved analytical method. No commenters provided a technical analysis indicating that one data set is more accurate. Given these comments, EPA has retained the approach of analyzing costs and benefits separately for each occurrence data set in today's final rule.

b. *Treatment of observed zeros.* One commenter remarked that the majority of samples in which no oocysts were detected (i.e., observed zeros) likely contained no oocysts in the volume assayed. This commenter was concerned with a parameter in EPA's occurrence analysis model for ''true zero,'' which characterizes the likelihood that a source water is entirely free of Cryptosporidium at all times. In EPA's model, the true zero parameter was assigned a value of 0.1 percent. As described in USEPA (2005b), EPA based this assumption on the finding that intensive sampling of surface waters usually detects Cryptosporidium, even in protected watersheds. The commenter concluded, however, that the true zero parameter resulted in the model assigning a value of at least 1 oocyst to 99.9 percent of samples.

EPA responds that the true zero parameter in the occurrence analysis model does not operate in this way. While the model is set-up to estimate mean source water concentrations and not the concentrations in individual volumes assayed, the model recognizes that the majority of samples in the ICR and ICRSS contained no oocysts. The model does assume that few, if any, of the source waters sampled in these surveys never contained a single oocyst (the meaning of the true zero parameter). EPA has clarified the definition of the true zero parameter in USEPA (2005b). EPA has also conducted a sensitivity analysis in which the true zero parameter was varied from values of 0 to 50 percent, with little effect on estimates of risk, benefit, and cost for today's rule.

2. Drinking Water Consumption

Two commenters were concerned with the distribution for drinking water consumption that EPA used in the proposed LT2ESWTR. This distribution, which was based on a 1994–1996 survey by the United States Department of Agriculture (USDA), reflects water consumption from all sources. Commenters recommended two modifications to this approach: (1) Adjust the distribution to account for factors like bottled water and boiled water use; and (2) use an alternative distribution from the USDA survey that reflects consumption of community water system (CWS) water only.

In response, EPA agrees that the distribution should be adjusted to remove consumption attributable to bottled water. For the consumption distribution in today's final rule, EPA subtracted bottled water usage, based on information in the USDA survey, which had the effect of reducing consumption by approximately 14 percent in comparison to the proposal. EPA does not have information on the effectiveness of heating water to make coffee or tea for inactivating Cryptosporidium and has not modified the consumption distribution on this basis.

EPA continues to believe that the USDA distribution for consumption of water from all sources, minus bottled water consumption, provides the best available estimate for consumption of water from CWSs for people served by CWSs. The USDA distribution for consumption of CWS water only, which a commenter recommended, includes people not served by CWSs (e.g., people with private wells). Inclusion these individuals has the effect of underestimating the consumption of CWS water for people served by CWSs in this distribution. In contrast, the distribution for consumption of water from all sources includes people not served by CWSs and the sources those people use (e.g., private wells). This avoids the problem of underestimating consumption for individuals served by CWS. Accordingly, EPA has retained the use of this distribution in today's final rule, with the adjustment stated previously for bottled water consumption.

3. Cryptosporidium Infectivity

In regard to Cryptosporidium infectivity (i.e., dose-response assessment), EPA received significant comment on limitations in the human feeding studies (e.g. representativeness of Cryptosporidium isolates used in the studies, numbers of subjects) and uncertainty in extrapolating from high study doses to low drinking water doses. EPA believes that the statistical analysis of dose-response data, as described in USEPA (2005a), properly accounted for these limitations and uncertainties.

The statistical models used by EPA treated the isolates studied as a random sample from a larger population of environmental isolates, treated the subjects studied as a random sample from the larger population of healthy individuals, and treated each individual's outcome as a chance event, where the infection probability is a function of the challenge dose. Collectively, these uncertainties contributed to the significant uncertainty in EPA's estimate of the likelihood of infection given one oocyst ingested.

Since the LT2ESWTR proposal, EPA has reviewed results from additional human feeding studies with Cryptosporidium isolates and analyzed data from these and the feeding studies considered for the proposal with additional dose-response models (USEPA 2005a). As described in Chapter 5 and Appendix N of the LT2ESWTR EA, the infectivity estimates from the proposal are near the middle of the range of estimates derived with the additional feeding study data and dose-response models. Further, the mean estimates from these new analyses fall within the 90th percentile uncertainty bounds for infectivity estimates from the proposal (USEPA 2005a). Consequently, EPA believes that the infectivity estimates from the additional feeding study data and dose-response models are consistent with and supportive of the estimates of infectivity from the proposal. Further, EPA's estimates of infectivity are consistent with data on the infectivity of Cryptosporidium in the 1993 Milwaukee outbreak (USEPA 2005a).

4. Valuation of Benefits

In the area of benefits valuation, EPA received significant public comment on the valuation of morbidity, valuation of lost time under the Enhanced COI approach, and unquantified benefits.

a. *Valuation of morbidity.* EPA received a comment that endemic cases that do not show up in public health surveillance data may be too mild (and perhaps even asymptomatic) to be economically significant. EPA believes endemic cases are significant in terms of public health risk and economic impacts. As discussed earlier, only a small fraction of the millions of cases of gastrointestinal illnesses are traced to a specific illness (such as cryptosporidiosis); yet endemic disease clearly exists and those illnesses, even if mild, have public health consequences and economic impacts (e.g., missed work). For example, the benefits model in the EA assumes that 88 percent of all cases are mild, and yet those illnesses represent significant impacts nationally. Further, the risk assessment model separately computes infections and illnesses. Thus, asymptomatic infections are excluded; only avoided illnesses are assigned monetary benefits.

b. *Valuation of lost time under the enhanced cost of illness (COI) approach.* One commenter extensively questioned the approach used to value lost leisure and nonwork time under the Enhanced COI approach, noting concerns about the relationship of the approach to standard economics practices, the plausibility of the resulting values, and the extent of peer review. The following discussion summarizes EPA's responses on these issues.

As discussed in detail in the EA (USEPA 2005a), EPA recognizes that the preferred approach for valuing health risk reductions is to rely on estimates of individual willingness to pay (WTP). In the absence of suitable WTP estimates, analysts often rely on approaches similar to the Traditional COI approach used for this rule, as noted by the commenter. However, empirical research as well as theoretic concerns suggest that these types of COI approaches will generally understate true WTP.

EPA designed the Enhanced COI approach to correct for one potential source of understatement—the impact of illness on unpaid work and leisure time. While the Enhanced COI approach is innovative, it is rooted in standard welfare economic theory and builds on approaches used to value time in numerous studies in the labor, transportation, recreation, and health economics literature. The commenter is concerned, however, that the Enhanced COI approach values nonwork time at a higher rate than many recreational studies, several of which value travel time at one-third of the wage rate. EPA's extensive review of the recreational literature suggests, however, that there is no consensus regarding the value of travel time, as discussed in the Appendix P of the EA (USEPA 2005a). In addition, travel has both pleasant and unpleasant aspects and hence may be valued less than other leisure activities, many of which may be valued at a rate higher than foregone wages.

To test the plausibility of the results, the commenter compares the value of a ''lifetime case'' of cryptosporidiosis to the value of statistical life (VSL) and suggests that the results (which show that such a case would be roughly 70 percent of VSL) are improbably high. However, EPA believes that this comparison is seriously flawed. There is no generally accepted standard for determining whether values for nonfatal risk reductions are ''reasonable'' compared to values for fatal risk reductions. In addition, the calculation of the value of a lifetime case of cryptosporidiosis contains several computational errors, and represents the loss of all waking time (not just losses attributable to cryptosporidiosis) and so is seriously overstated. Perhaps most important, the approach used to value

time losses in the Enhanced COI estimate is appropriate only for marginal changes in time use; it is not appropriate for the types of lifetime changes considered in the comparison.

The Enhanced COI estimates are based on an approach developed in the EPA report, Valuing Time Losses Due to Illness under the 1996 Amendments to the Safe Drinking Water Act (USEPA 2005e). This report has been subject to two rounds of independent peer review. In conclusion, EPA believes that including the Enhanced COI in conjunction with the Traditional COI is justified theoretically and that including both measures increases EPA's ability to understand the impacts of the rule.

VII. Statutory and Executive Order Reviews

A. Executive Order 12866: Regulatory Planning and Review

Under Executive Order 12866, [58 FR 51735, (October 4, 1993)] the Agency must determine whether the regulatory action is ''significant'' and therefore subject to OMB review and the requirements of the Executive Order. The Order defines ''significant regulatory action'' as one that is likely to result in a rule that may:

(1) Have an annual effect on the economy of $100 million or more or adversely affect in a material way the economy, a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local, or Tribal governments or communities;

(2) Create a serious inconsistency or otherwise interfere with an action taken or planned by another agency;

(3) Materially alter the budgetary impact of entitlements, grants, user fees, or loan programs or the rights and obligations of recipients thereof; or

(4) Raise novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles set forth in the Executive Order.

Pursuant to the terms of Executive Order 12866, it has been determined that this rule is a ''significant regulatory action'' because it may have an annual effect on the economy of $100 million or more (estimated annual costs are $93 to 133 million and $107 to 150 million at 3 and 7 percent discount rates, respectively). As such, this action was submitted to OMB for review. Changes made in response to OMB suggestions or recommendations are documented in the public record.

B. Paperwork Reduction Act

The Office of Management and Budget (OMB) has approved the information collection requirements contained in this rule under the provisions of the *Paperwork Reduction Act,* 44 U.S.C. 3501 *et seq.* and has assigned OMB control number 2040–0266.

The information collected as a result of this rule will allow the States and EPA to determine appropriate requirements for specific PWSs and to evaluate compliance with the rule. For the first 3 years after LT2ESWTR promulgation, the major information requirements concern monitoring activities and compliance tracking. The information collection requirements are mandatory (40 CFR part 141) and the information collected is not confidential.

The estimate of annual average burden hours for the LT2ESWTR during the first three years following promulgation is 141,295 hours. The annual average cost estimate is $4.4 million for labor and $7 million per year for operation and maintenance including lab costs (which is a purchase of service). The burden hours per response is 0.63 hours and the cost per response is $50.35. The frequency of response (average responses per respondent) is 90.3, annually. The estimated number of likely respondents is 2,503 (the product of burden hours per response, frequency, and respondents does not total the annual average burden hours due to rounding). Note that the burden hour estimates for the first 3-year cycle include some large PWS but not small PWS monitoring. Conversely, burden estimate for the second 3-year cycle will include remaining monitoring for large systems (those serving between 10,000 and 49,999 people) and small PWS monitoring, but not for large PWS serving 50,000 or more, which will have been completed by then.

Burden means the total time, effort, or financial resources expended by persons to generate, maintain, retain, or disclose or provide information to or for a Federal agency. This includes the time needed to review instructions; develop, acquire, install, and utilize technology and systems for the purposes of collecting, validating, and verifying information, processing and maintaining information, and disclosing and providing information; adjust the existing ways to comply with any previously applicable instructions and requirements; train personnel to be able to respond to a collection of information; search data sources; complete and review the collection of information; and transmit or otherwise disclose the information.

An agency may not conduct or sponsor, and a person is not required to respond to a collection of information unless it displays a currently valid OMB control number. The OMB control numbers for EPA's regulations in 40 CFR are listed in 40 CFR part 9. In addition, EPA is amending the table in 40 CFR part 9 of currently approved OMB control numbers for various regulations to list the regulatory citations for the information requirements contained in this final rule.

C. Regulatory Flexibility Act

The Regulatory Flexibility Act (RFA) generally requires an agency to prepare a regulatory flexibility analysis for any rule subject to notice and comment rulemaking requirements under the Administrative Procedure Act or other statute unless the agency certifies that the rule will not have a significant economic impact on a substantial number of small entities. Small entities include small businesses, small organizations, and small governmental jurisdictions.

The RFA provides default definitions for each type of small entity. Small entities are defined as: (1) a small business as defined by the Small Business Administrations's (SBA) regulations at 13 CFR 121.201; (2) a small governmental jurisdiction that is a government of a city, county, town, school district or special district with a population of less than 50,000; and (3) a small organization that is any ''not-for-profit enterprise which is independently owned and operated and is not dominant in its field.'' However, the RFA also authorizes an agency to use alternative definitions for each category of small entity, ''which are appropriate to the activities of the agency'' after proposing the alternative definition(s) in the **Federal Register** and taking comment. 5 U.S.C. 601(3)–(5). In addition, to establish an alternative small business definition, agencies must consult with SBA's Chief Counsel for Advocacy.

For purposes of assessing the impacts of today's rule on small entities, EPA considered small entities to be public water systems serving 10,000 or fewer persons. As required by the RFA, EPA proposed using this alternative definition in the **Federal Register** (63 FR 7620, February 13, 1998), requested public comment, consulted with the Small Business Administration (SBA), and finalized the alternative definition in the Consumer Confidence Reports regulation (63 FR 44511, August 19, 1998). As stated in that Final Rule, the alternative definition is applied to this regulation as well.

After considering the economic impacts of today's final rule on small entities, I certify that this action will not have a significant economic impact on a substantial number of small entities. The small entities directly regulated by this final rule are PWSs serving fewer than 10,000 people. We have determined that 152 of the 6,574 small PWSs, or 2.3 percent, regulated by the LT2ESWTR will experience an impact of 1 percent or greater of average annual revenues; further, 18 PWSs, which are 0.3 percent of the small PWSs regulated by this rule, will experience an impact of 3 percent or greater of average annual revenues (see Table VII.C–1).

TABLE VII.C–1.—ANNUALIZED COMPLIANCE COST AS A PERCENTAGE OF REVENUES FOR SMALL ENTITIES (2003$)

PWSs by ownership type and system size	Number of small systems	Percent of small systems	Average annual estimated revenues per system($)	Systems experiencing costs of ≥1% of their revenues		Systems experiencing costs of ≥3% of their revenues	
				Number of systems	Percent of systems	Number of systems	Percent of systems
	A	B	C	D=A*E	E	F=A*G	G
Small Government PWSs	2,827	43	2,649,186	65	2.3	8	0.3
Small Business PWSs	2,452	37	2,555,888	57	2.3	7	0.3
Small Organization PWSs	1,295	20	4,750,838	5	0.4	2	0.1
All Small Entity PWSs	6,574	100	2,981,331	152	2.3	18	0.3

Note: Detail may not add due to independent rounding. Data are based on the means of the highest modeled distributions using Information Collection Rule occurrence data set. Costs are discounted at 3 percent, summed to present value, and annualized over 25 years. Source: Chapter 7 and Appendix H of the LT2ESWTR EA (USEPA 2005a).

Although this final rule will not have a significant economic impact on a substantial number of small entities, EPA nonetheless has tried to reduce the impact of this rule on small entities. The LT2ESWTR contains a number of provisions to minimize the impact of the rule on PWSs generally, and on small PWSs in particular. The risk-targeted approach of the LT2ESWTR will impose additional treatment requirements only on the subset of PWSs with the highest vulnerability to Cryptosporidium, as indicated by source water pathogen levels. This approach will spare the majority of PWSs from the cost of installing additional treatment. Also, development of the microbial toolbox under the LT2ESWTR will provide both large and small PWSs with broad flexibility in selecting cost-effective compliance options to meet additional treatment requirements.

Small PWSs will monitor for E. coli as a screening analysis for source waters with low levels of fecal contamination. Cryptosporidium monitoring will only be required of small PWSs if they exceed the E. coli trigger value. Because E. coli analysis is much cheaper than Cryptosporidium analysis, the use of E. coli as a screen will significantly reduce monitoring costs for the majority of small PWSs. Further, small PWSs will not be required to initiate their monitoring until large PWS monitoring has been completed. This will provide small PWSs with additional time to become familiar with the rule and to prepare for monitoring and other compliance activities.

Funding may be available from programs administered by EPA and other Federal agencies to assist small PWSs in complying with the LT2ESWTR. The Drinking Water State Revolving Fund (DWSRF) assists PWSs with financing the costs of infrastructure needed to achieve or maintain compliance with SDWA requirements. Through the DWSRF, EPA awards capitalization grants to States, which in turn can provide low-cost loans and other types of assistance to eligible PWSs. Loans made under the program can have interest rates between 0 percent and market rate and repayment terms of up to 20 years. States prioritize funding based on projects that address the most serious risks to human health and assist PWSs most in need. Congress provided $1.275 billion for the DWSRF program in fiscal year 1997, and has provided an additional $4.113 billion for the DWSRF program for fiscal years 1999 through 2003.

The DWSRF places an emphasis on small and disadvantaged communities. States must provide a minimum of 15% of the available funds for loans to small communities. A State has the option of providing up to 30% of the grant awarded to the State to furnish additional assistance to State-defined disadvantaged communities. This assistance can take the form of lower interest rates, principal forgiveness, or negative interest rate loans. The State may also extend repayment terms of loans for disadvantaged communities to up to 30 years. A State can set aside up to 2% of the grant to provide technical assistance to PWSs serving communities with populations fewer than 10,000.

In addition to the DWSRF, money is available from the Department of Agriculture's Rural Utility Service (RUS) and Housing and Urban Development's Community Development Block Grant (CDBG) program. RUS provides loans, guaranteed loans, and grants to improve, repair, or construct water supply and distribution systems in rural areas and towns of up to 10,000 people. In fiscal year 2003, RUS had over $1.5 billion of available funds for water and environmental programs. The CDBG program includes direct grants to States, which in turn are awarded to smaller communities, rural areas, and coloñas in Arizona, California, New Mexico, and Texas and direct grants to U.S. territories and trusts. The CDBG budget for fiscal year 2003 totaled over $4.4 billion.

Although not required by the RFA to convene a Small Business Advocacy Review (SBAR) Panel because EPA determined that the proposed rule would not have a significant economic impact on a substantial number of small entities, EPA did convene a panel to obtain advice and recommendations from representatives of the small entities potentially subject to this rule's requirements. For a description of the SBAR Panel and stakeholder recommendations, please see the proposed rule (USEPA 2003a).

D. Unfunded Mandates Reform Act

Title II of the Unfunded Mandates Reform Act of 1995 (UMRA), Public Law 104–4, establishes requirements for Federal agencies to assess the effects of their regulatory actions on State, local,

and Tribal governments and the private sector. Under section 202 of the UMRA, EPA generally must prepare a written statement, including a cost-benefit analysis, for proposed and final rules with ''Federal mandates'' that may result in expenditures to State, local and Tribal governments, in the aggregate, or to the private sector, of $100 million or more in any one year. Before promulgating an EPA rule for which a written statement is needed, section 205 of the UMRA generally requires EPA to identify and consider a reasonable number of regulatory alternatives and adopt the least costly, most cost-effective or least burdensome alternative that achieves the objectives of the rule. The provisions of section 205 do not apply when they are inconsistent with applicable law. Moreover, section 205 allows EPA to adopt an alternative other than the least costly, most cost-effective or least burdensome alternative if the Administrator publishes with the final rule an explanation why that alternative was not adopted.

Before EPA establishes any regulatory requirements that may significantly or uniquely affect small governments, including Tribal governments, it must have developed under section 203 of the UMRA a small government agency plan. The plan must provide for notifying potentially affected small governments, enabling officials of affected small governments to have meaningful and timely input in the development of EPA regulatory proposals with significant Federal intergovernmental mandates, and informing, educating, and advising small governments on compliance with the regulatory requirements.

EPA has determined that this rule contains a Federal mandate that may result in expenditures of $100 million or more for State, local, and Tribal governments, in the aggregate, or the private sector in any one year. Accordingly, EPA has prepared under section 202 of the UMRA a written statement which is summarized below.

Table VII.D–1 illustrates the annualized public and private costs for the LT2ESWTR.

Table VII.D-1.– Public and Private Costs of the LT2ESWTR

	Range of Annualized Costs (Million$, 2003$)						Percent of Total Cost		
	3% Discount Rate			7% Discount Rate					
Publicly Owned PWS Costs	$57.4	-	$82.7	$65.9	-	$88.6	61.8%	-	62.0%
State Costs	$1.1	-	$1.2	$1.4	-	1.4	1.2%	-	0.9%
Tribal Costs	$0.2	-	$0.2	$0.2	-	$0.3	0.2%	-	0.2%
Total Public Costs	**$58.6**	**-**	**84.1**	**$67.5**	**-**	**90.3**	**63.1%**	**-**	**63.0%**
Total Private Costs	**$34.3**	**-**	**49.4**	**$39.3**	**-**	**60.2**	**36.9%**	**-**	**37.0%**
Total Costs	**$92.9**	**-**	**$133.4**	**$106.8**	**-**	**150.5**	**100.0%**	**-**	**100.0%**

Note: The ranges represent the ICRSSL (lowest) and Information Collection Rule (highest) modeled *Cryptosporidium* occurrence distributions. Detail may not add due to independent rounding.
Source: The LT2ESWTR Economic Analysis (USEPA 2005a).

A more detailed description of this analysis is presented in Economic Analysis for the LT2ESWTR (USEPA 2005a).

As noted in section III, today's final rule is promulgated pursuant to section 1412 (b)(1)(A) of the Safe Drinking Water Act (SDWA), as amended in 1996, which directs EPA to promulgate a national primary drinking water regulation for a contaminant if EPA determines that the contaminant may have an adverse effect on the health of persons, occurs in PWSs with a frequency and at levels of public health concern, and regulation presents a meaningful opportunity for health risk reduction.

Section VI of this preamble discusses the cost and benefits associated with the LT2ESWTR. Details are presented in the Economic Analysis for the LT2ESTWR (USEPA 2005a). EPA quantified costs and benefits for four regulatory alternatives. The four alternatives are described in section VI. Table VII.D–2 summarizes the range of annual costs and benefits for each alternative.

Table VII.D-2.– Annual Benefits and Costs of Rule Alternatives ($million, 2003$)

Regulatory Alternative	Enhanced COI Range of Annualized Benefits (3%)	Traditional COI Range of Annualized Benefits (3%)	Enhanced COI Range of Annualized Benefits (7%)	Traditional COI Range of Annualized Benefits (7%)	Range of Anualized Costs (3%)	Range of Anualized Costs (7%)
Alternative A1	221 - 2891	160 - 2093	221 - 2341	130 - 1700	403 - 403	437 - 436
Alternative A2	191 - 2851	139 - 2066	154 - 2309	113 - 1678	123 - 163	139 - 182
Alternative A3 (Preferred Alternative)	177 - 2822	130 - 2047	144 - 2286	105 - 1662	93 - 133	107 - 150
Alternative A4	155 - 2661	115 - 1937	126 - 2156	93 - 1574	57 - 81	68 - 93

Source: The *LT2ESWTR Economic Analysis* (USEPA 2005a).

To meet the UMRA requirement in section 202, EPA analyzed future compliance costs and possible disproportionate budgetary effects. The Agency believes that the cost estimates, indicated earlier and discussed in more detail in section VI of this preamble, accurately characterize future compliance costs of today's rule.

In analyzing disproportionate impacts, EPA considered the impact on (1) different regions of the United States, (2) State, local, and Tribal governments, (3) urban, rural and other types of communities, and (4) any segment of the private sector. This analysis is presented in Chapter 7 of Economic Analysis for the LT2ESWTR (USEPA 2005a).

EPA has concluded that the LT2ESWTR will not cause a disproportionate budgetary effect. This rule imposes the same requirements on PWSs nationally and does not disproportionately affect any segment. This rule will treat similarly situated PWSs (in terms of size, water quality, available data, installed technology, and presence of uncovered finished storage facilities) in similar (proportionate) ways, without regard to geographic location, type of community, or segment of industry. The LT2ESWTR is a rule where requirements are proportionate to risk. Although some groups may have differing budgetary effects as a result of the LT2ESWTR, those costs are proportional to the need for greater information (monitoring) and risk posed (degree of treatment required). The variation in cost between large and small PWSs is due to economies of scale (a larger PWS can distribute cost across more customers). Regions will have varying impacts due to the number of affected PWSs.

Under UMRA section 202, EPA is required to estimate the potential macro-economic effects of the regulation. These types of effects include those on productivity, economic growth, full employment, creation of productive jobs, and international competitiveness. Macro-economic effects tend to be measurable in nationwide econometric models only if the economic impact of the regulation reaches 0.25 percent to 0.5 percent of Gross Domestic Product (GDP). In 2003, real GDP was $10,398 billion, so a rule would have to cost at least $26 billion to have a measurable effect. A regulation with a smaller aggregate effect is unlikely to have any measurable impact unless it is highly focused on a particular geographic region or economic sector.

The macro-economic effects on the national economy from the LT2ESWTR should not have a measurable effect because the total annual costs for today's rule range from $93 million to $133 million based on median Cryptosporidium occurrence distributions from the ICRSSL and Information Collection Rule data sets and a discount rate of 3 percent ($107 to $150 million at a 7 percent discount rate). These annualized figures will remain constant over the 25-year implementation period that was evaluated, while GDP will probably continue to rise. Thus, the LT2ESWTR costs as a percentage of the national GDP will only decline over time. Costs will not be highly focused on a particular geographic region or sector.

Consistent with the intergovernmental consultation provisions of section 204 of the UMRA, EPA initiated consultations with the governmental entities affected by this rule prior to the proposal. A description of the consultations is found in the proposed rule (USEPA 2003a).

As required under section 205 of UMRA, EPA considered several regulatory alternatives to address PWSs at risk for contamination by microbial pathogens, specifically including Cryptosporidium. A detailed discussion of these alternatives can be found in section VI of the preamble and also in the Economic Analysis for the LT2ESWTR (USEPA 2005a).

Among the regulatory alternatives considered for the LT2ESWTR, as described in section VI, EPA believes the alternative in today's rule is the most cost-effective that achieves the objectives of the rule. The objective of the LT2ESWTR is to achieve feasible risk reduction from Cryptosporidium and other pathogens in vulnerable PWSs where current regulations do not provide sufficient protection.

EPA evaluated a less costly and less burdensome alternative. However, that alternative would provide no benefit to several thousand consumers who, under the alternative in today's final rule, will receive benefits that most likely exceed their costs, based on EPA estimates. This is illustrated in the LT2ESWTR Economic Analysis (USEPA 2005a). By failing to reduce risk for consumers where additional treatment requirements would be cost-effective, the less costly alternative does not appear to achieve the objectives of the LT2ESWTR.

The other alternatives considered by the Agency achieve the objectives of the rule, but are more costly, more burdensome, and potentially less cost-effective. The alternative in today's rule targets additional treatment requirements to PWSs with the highest vulnerability to Cryptosporidium and maximizes net benefits under a broad range of conditions (USEPA 2005a). Consequently, EPA has found the alternative in today's rule to be the most cost-effective among those that achieve the objectives of the rule.

EPA has determined that this rule contains no regulatory requirements that might significantly or uniquely affect small governments. Thus, today's rule is not subject to the requirements of section 203 of UMRA. As described in section VII.C, EPA has certified that today's rule will not have a significant economic impact on a substantial number of small entities. Average annual expenditures for small PWSs to comply with the LT2ESWTR range from

$8.1 to $13.4 million at a 3% discount rate and $8.3 to $13.5 million at a 7% discount rate. While the treatment requirements of the LT2ESWTR apply uniformly to both small and large PWSs, large PWSs bear a majority of the total costs of compliance with the rule. This is due to the fact that large PWSs treat a majority of the drinking water that originates from surface water sources.

E. Executive Order 13132: Federalism

Executive Order 13132, entitled ''Federalism'' (64 FR 43255, August 10, 1999), requires EPA to develop an accountable process to ensure ''meaningful and timely input by State and local officials in the development of regulatory policies that have federalism implications.'' ''Policies that have federalism implications'' is defined in the Executive Order to include regulations that have ''substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government.''

Under Executive Order 13132, EPA may not issue a regulation that has federalism implications, that imposes substantial direct compliance costs, and that is not required by statute, unless the Federal government provides the funds necessary to pay the direct compliance costs incurred by State and local governments, or EPA consults with State and local officials early in the process of developing the regulation.

EPA has concluded that this final rule may have federalism implications, because it may impose substantial direct compliance costs on State or local governments, and the Federal government will not provide the funds necessary to pay those costs. The final rule may result in expenditures by State, local, and Tribal governments, in the aggregate of $100 million or more in any one year. Costs are estimated to range from $93 to $133 million at a 3 percent discount rate and $107 to $150 million using a 7 percent discount rate based on the median distribution modeled from ICRSSL and Information Collection Rule Cryptosporidium occurrence data sets. Accordingly, EPA provides the following federalism summary impact statement as required by section 6(b) of Executive Order 13132.

EPA consulted with representatives of State and local officials early in the process of developing today's rule to permit them to have meaningful and timely input into its development. As described in the proposed rule (USEPA 2003a), this consultation included State and local government representatives on the Stage 2 M–DBP Federal Advisory Committee (whose recommendations were largely adopted in today's rule), the representatives from small local governments to the SBAR panel, a meeting with representatives from the Association of State Drinking Water Administrators, the National Governors' Association, the National Conference of State Legislatures, the International City/County Management Association, the National League of Cities, the County Executives of America, and health departments, consultation with Tribal governments at four meetings and through the Advisory Committee process, and comments from State and local governments on a pre-proposal draft of the LT2ESWTR.

Representatives of State and local officials were generally concerned with ensuring that drinking water regulations are adequately protective of public health and that any additional regulations achieve significant health benefits in return for required expenditures. They were specifically concerned with the burden of the rule, both in cost and technical complexity, giving flexibility to PWSs and States, balancing the control of microbial risks and DBP risks, funding for implementing new regulations, equal protection for small PWSs, and early implementation of monitoring by large PWSs.

EPA has concluded that the LT2ESWTR is needed to reduce the public health risk associated with Cryptosporidium in drinking water. As shown in section VI, estimated benefits for the rule are significantly higher than costs. Further, EPA believes that today's rule addresses many of the concerns expressed by representatives of government officials.

Under the LT2ESWTR, expenditures for additional treatment are targeted to the fraction of PWSs with the highest vulnerability to Cryptosporidium, thereby minimizing burden for the majority of PWSs, which will not be required to provide additional treatment. The microbial toolbox of compliance options will provide flexibility to PWSs in meeting additional treatment requirements, and States have the flexibility to award treatment credits based on site-specific demonstrations. Disinfection profiling provisions are intended to ensure that PWSs do not reduce microbial protection as they take steps to reduce exposures to DBPs.

The LT2ESWTR achieves equal public health protection for small PWSs. However, the use of E. coli monitoring by small PWSs as a screening analysis to determine the need for Cryptosporidium monitoring will reduce monitoring costs for most small PWSs. Capital projects related to the rule will be eligible for funding from the Drinking Water State Revolving Fund, which includes specific funding for small communities. EPA is planning to support the initial monitoring by large PWSs that takes place within the first few years after rule promulgation. This will substantially reduce the burden on States associated with early implementation of monitoring requirements.

In the spirit of Executive Order 13132, and consistent with EPA policy to promote communications between EPA and State and local governments, EPA specifically solicited comment on the proposed rule from State and local officials.

As required by section 8(a) of Executive Order 13132, EPA included a certification from its Federalism Official stating that EPA had met the Executive Order's requirements in a meaningful and timely manner, when it sent the draft of this final rule to OMB for review pursuant to Executive Order 12866. A copy of this certification has been included in the public version of the official record for this final rule.

F. Executive Order 13175: Consultation and Coordination With Indian Tribal Governments

Executive Order 13175, entitled ''Consultation and Coordination with Indian Tribal Governments'' (65 FR 67249, November 9, 2000), requires EPA to develop ''an accountable process to ensure meaningful and timely input by tribal officials in the development of regulatory policies that have tribal implications.'' Under Executive Order 13175, EPA may not issue a regulation that has Tribal implications, that imposes substantial direct compliance costs, and that is not required by statute, unless the Federal government provides the funds necessary to pay the direct compliance costs incurred by Tribal governments, or EPA consults with Tribal officials early in the process of developing the proposed regulation and develops a Tribal summary impact statement.

EPA has concluded that this final rule may have Tribal implications, because it may impose substantial direct compliance costs on Tribal governments, and the Federal government will not provide the funds necessary to pay those costs. EPA has identified 93 Tribal water systems serving a total population of 82,216 that may be subject to the LT2ESWTR. They will bear an estimated total annualized cost of $207,105 at a 3 percent discount rate ($309,583 at 7 percent) to

implement this rule. Estimated mean annualized cost per system ranges from $1,944 to $7,068 at a 3 percent discount rate ($2,905 to $10,681 at 7 percent) depending on PWS size (see Chapter 7 of the LT2ESWTR Economic Analysis (USEPA 2005a) for details). Accordingly, EPA provides the following Tribal summary impact statement as required by section 5(b).

EPA consulted with Tribal officials early in the process of developing this regulation to permit them to have meaningful and timely input into its development. This consultation is described in the proposed rule (USEPA 2003a). Tribal officials were represented on the M–DBP Advisory Committee.

As required by section 7(a), EPA's Tribal Consultation Official has certified that the requirements of the Executive Order have been met in a meaningful and timely manner. A copy of this certification is included in the docket for this rule.

G. Executive Order 13045: Protection of Children From Environmental Health and Safety Risks

Executive Order 13045: ''Protection of Children from Environmental Health Risks and Safety Risks'' (62 FR 19885, April 23, 1997) applies to any rule that: (1) is determined to be ''economically significant'' as defined under Executive Order 12866, and (2) concerns an environmental health or safety risk that EPA has reason to believe may have a disproportionate effect on children. If the regulatory action meets both criteria, the Agency must evaluate the environmental health or safety effects of the planned rule on children and explain why the planned regulation is preferable to other potentially effective and reasonably feasible alternatives considered by the Agency.

This final rule is subject to the Executive Order because it is an economically significant regulatory action as defined in Executive Order 12866, and we believe that the environmental health or safety risk addressed by this action may have a disproportionate effect on children. Accordingly, we have evaluated the environmental health or safety effects of Cryptosporidium on children. The results of this evaluation are contained in Cryptosporidium: Risk for Infants and Children (USEPA 2001d), which is available in the public docket for this action, and are summarized in this section of the preamble. Further, while available information is not adequate to conduct a quantitative risk assessment specifically for children, EPA has assessed the risk associated with Cryptosporidium in drinking water for the general population, including children. This assessment is described in the Economic Analysis for the LT2ESWTR (USEPA 2005a) and is summarized in section VI of this preamble.

Children's Environmental Health

Cryptosporidiosis in children is similar to adult disease (USEPA 2001d). Diarrhea is the most common symptom. Other common symptoms in otherwise healthy (i.e., immunocompetent) children include anorexia, vomiting, abdominal pain, fever, dehydration and weight loss.

The risk of illness and death due to cryptosporidiosis depends on several factors, including age, nutrition, exposure, genetic variability, disease and the immune status of the individual. Mortality resulting from diarrhea generally occurs at a greater rate among the very young and elderly (Gerba et al., 1996). During the 1993 Milwaukee drinking water outbreak, associated mortalities in children were reported. Also, children with laboratory-confirmed cryptosporidiosis were more likely to have an underlying disease that altered their immune status (Cicirello et al., 1997). In that study, the observed association between increasing age of children and increased numbers of laboratory-confirmed cryptosporidiosis suggested to the authors that the data are consistent with increased tap water consumption of older children. Asymptomatic infection can have a substantial effect on childhood growth (Bern et al., 2002).

Cryptosporidiosis appears to be more prevalent in populations, such as children, that may not have established immunity against the disease and may be in greater contact with environmentally contaminated surfaces (DuPont et al., 1995). In the United States, children aged one to four years are more likely than adults to have the disease. The most recent reported data on cryptosporidiosis shows the occurrence rate (for the year 1999) is higher in children ages one to four (3.03 incidence rate per 100,000) than in any adult age group (CDC, 2001). Evidence from blood sera antibodies collected from children during the 1993 Milwaukee outbreak suggest that children had greater levels of Cryptosporidium infection than predicted for the general community (based on the random-digit dialing telephone survey method) (McDonald et al., 2001).

Data indicate a lower incidence of cryptosporidiosis infection during the first year of life. This is attributed to breast-fed infants consuming less tap water and, hence, having less exposure to Cryptosporidium, as well as the possibility that mothers confer short term immunity to their children. For example, in a survey of over 30,000 stool sample analyses from different patients in the United Kingdom, the one to five year age group suffered a much higher infection rate than individuals less than one year of age. For children under one year of age, those older than six months of age showed a higher rate of infection than individuals aged less than six months (Casemore, 1990). Similarly, in the U.S., of 2,566 reported Cryptosporidium illnesses in 1999, 525 occurred in ages one to four (incidence rate of 3.03 per 100,000) compared with 58 cases in infants under one year (incidence rate of 1.42 per 100,000) (CDC, 2001).

An infected child may spread the disease to other children or family members (Heijbel et al., 1987, Osewe et al., 1996). Millard et al. (1994) documented greater household secondary transmission of cryptosporidiosis from children than from adults to household and other close contacts. Children continued to shed oocysts for more than two weeks (mean 16.5 days) after diarrhea cessation (Tangerman et al., 1991).

While Cryptosporidium may have a disproportionate effect on children, available data are not adequate to distinctly assess the health risk for children resulting from Cryptosporidium-contaminated drinking water. In assessing risk to children when evaluating regulatory alternatives for the LT2ESWTR, EPA assumed the same risk for children as for the population as a whole.

Section VI of this preamble presents the regulatory alternatives that EPA evaluated for the proposed LT2ESWTR. Among the four alternatives the Agency considered, three involved a risk-targeting approach in which additional Cryptosporidium treatment requirements are based on source water monitoring results. A fourth alternative involved additional treatment requirements for all PWSs. The alternative requiring additional treatment by all PWSs was not selected because of concerns about feasibility and because it imposed costs but provided few benefits to PWSs with high quality source water (i.e., relatively low Cryptosporidium risk). The three risk-targeting alternatives were evaluated based on several factors, including costs, benefits, net benefits, feasibility of implementation, and other specific impacts (e.g., impacts on small PWSs or sensitive subpopulations).

The alternative that today's final rule establishes was recommended by the M–DBP Federal Advisory Committee and selected by EPA as the Preferred Regulatory Alternative because it was deemed feasible and provides significant public health benefits in terms of avoided illnesses and deaths. EPA's analysis of benefits and costs indicates that this alternative ranks highly among those evaluated with respect to maximizing net benefits, as shown in the LT2ESWTR Economic Analysis (USEPA 2005a). This document is available in the docket for this action.

The result of the LT2ESWTR will be a reduction in the risk of illness for the entire population, including children. Because available evidence indicates that children may be more vulnerable to cryptosporidiosis than the rest of the population, the LT2ESWTR may, therefore, result in greater risk reduction for children than for the general population.

H. Executive Order 13211: Actions That Significantly Affect Energy Supply, Distribution, or Use

This rule is not a ''significant energy action'' as defined in Executive Order 13211, ''Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use'' (66 FR 28355 (May 22, 2001)) because it is not likely to have a significant adverse effect on the supply, distribution, or use of energy. This determination is based on the following analysis.

The first consideration is whether the LT2ESWTR would adversely affect the supply of energy. The LT2ESWTR does not regulate power generation, either directly or indirectly. The public and private utilities that the LT2ESWTR regulates do not, as a rule, generate power. Further, the cost increases borne by customers of water utilities as a result of the LT2ESWTR are a low percentage of the total cost of water, except for a very few small PWSs that might install advanced technologies and then need to spread that cost over a narrow customer base. Therefore, the customers that are power generation utilities are unlikely to face any significant effects as a result of the LT2ESWTR. In sum, the LT2ESWTR does not regulate the supply of energy, does not generally regulate the utilities that supply energy, and is unlikely to affect significantly the customer base of energy suppliers. Thus, the LT2ESWTR would not translate into adverse effects on the supply of energy.

The second consideration is whether the LT2ESWTR would adversely affect the distribution of energy. The LT2ESWTR does not regulate any aspect of energy distribution. The utilities that are regulated by the LT2ESWTR already have electrical service. As derived later in this section, the final rule is projected to increase peak electricity demand at water utilities by only 0.036 percent. Therefore, EPA estimates that the existing connections are adequate and that the LT2ESWTR has no discernable adverse effect on energy distribution.

The third consideration is whether the LT2ESWTR would adversely affect the use of energy. Because some drinking water utilities are expected to add treatment technologies that use electrical power, this potential impact is evaluated in more detail. The analyses that underlay the estimation of costs for the LT2ESWTR are national in scope and do not identify specific plants or utilities that may install treatment in response to the rule. As a result, no analysis of the effect on specific energy suppliers is possible with the available data. The approach used to estimate the impact of energy use, therefore, focuses on national-level impacts. The analysis estimates the additional energy use due to the LT2ESWTR, and compares that to the national levels of power generation in terms of average and peak loads.

The first step in the analysis is to estimate the energy used by the technologies expected to be installed as a result of the LT2ESWTR. Energy use is not directly stated in Technologies and Costs for Control of Microbial Contaminants and Disinfection By-Products (USEPA 2003c), but the annual cost of energy for each technology addition or upgrade necessitated by the LT2ESWTR is provided. An estimate of plant-level energy use is derived by dividing the total energy cost per plant for a range of flows by an average national cost of electricity of $0.070/kWh (USDOE 2004a). These calculations are shown in detail in Chapter 7 of the Economic Analysis for the LT2ESWTR (USEPA 2005a). The energy use per plant for each flow range and technology is then multiplied by the number of plants predicted to install each technology in a given flow range. The energy requirements for each flow range are then added to produce a national total. No electricity use is subtracted to account for the technologies that may be replaced by new technologies, resulting in a conservative estimate of the increase in energy use. Results of the analysis are shown in Table VII.H–1 for each of the modeled Cryptosporidium occurrence distributions. The incremental national annual energy usage is estimated at 165 million megawatt-hours (mW) based on the modeled Information Collection Rule occurrence distribution.

Table VII.H-1.– Total Increased Annual National Energy Usage Attributable to the LT2ESWTR

Technology	Plants Selecting Technology	Total Annual Energy Required (kWh/yr)
	A	B
UV	1,038	100,829,791
O_3 (0.5 log)	27	20,617,993
O_3 (1.0 log)	18	18,827,749
O_3 (2.0 log)	14	16,245,643
ME/UF	37	7,343,320
Bag Filters	1,523	1,605,380
Cartridge Filters	209	82,022
Total	2,867	165,551,898

Source: The *LT2ESWTR Economic Analysis* (USEPA 2005a).

To determine if the additional energy required for PWSs to comply with the rule would have a significant adverse effect on the use of energy, the numbers in Table VII.H–1 are compared to the national production figures for electricity. According to the U.S. Department of Energy's Information Administration, electricity producers generated 3,848 million mW of electricity in 2003 (USDOE 2004b). Therefore, even using the highest assumed energy use for the LT2ESWTR, the rule when fully implemented would result in only a 0.004 percent increase in annual average energy use.

In addition to average energy use, the impact at times of peak power demand is important. To examine whether increased energy usage might significantly affect the capacity margins of energy suppliers, their peak season generating capacity reserve was compared to an estimate of peak incremental power demand by water utilities.

Both energy use and water use are highest in the summer months, so the most significant effects on supply would be seen then. In the year of 2003, U.S. generation capacity exceeded consumption by 15 percent, or approximately 160,00 mW (USDOE EIA 2004b). Assuming around-the-clock operation of water treatment plants, the total energy requirement can be divided by 8,760 hours per year to obtain an average power demand of 19 mW for the modeled Information Collection Rule occurrence distribution. A more detailed derivation of this value is shown in Chapter 7 of the Economic Analysis for the LT2ESWTR (USEPA 2005a). Assuming that power demand is proportional to water flow through the plant, and that peak flow can be as high as twice the average daily flow during the summer months, about 38 mW could be needed for treatment technologies installed to comply with the LT2ESWTR. This is only 0.024 percent of the capacity margin available at peak use.

Although EPA recognizes that not all areas have a 15 percent capacity margin and that this margin varies across regions and through time, this analysis reflects the effect of the rule on national energy supply, distribution, or use. While certain areas, notably California, have experienced shortfalls in generating capacity in the recent past, a peak incremental power requirement of 38 mW nationwide is not likely to significantly change the energy supply, distribution, or use in any given area. Considering this analysis, EPA has concluded that LT2ESWTR is not likely to have a significant adverse effect on the supply, distribution, or use of energy.

I. National Technology Transfer and Advancement Act

As noted in the proposed rule, Section 12(d) of the National Technology Transfer and Advancement Act (''NTTAA'') of 1995, Public Law 104–113, section 12(d) (15 U.S.C. 272 note) directs EPA to use voluntary consensus standards in its regulatory activities unless to do so would be inconsistent with applicable law or otherwise impractical. Voluntary consensus standards are technical standards (*e.g.*, materials specifications, test methods, sampling procedures, and business practices) that are developed or adopted by voluntary consensus standard bodies. The NTTAA directs EPA to provide Congress, through OMB, explanations when the Agency decides not to use available and applicable voluntary consensus standards.

This rulemaking involves technical standards. EPA has decided to use methods previously approved in 40 CFR 136.3 for the analysis of E. coli in surface waters. These include several voluntary consensus methods that were developed or adopted by the following organizations: American Public Health Association in Standard Methods for the Examination of Water and Wastewater, 20th, 19th, and 18th Editions, the American Society of Testing Materials in Annual Book of ASTM Standards—Water and Environmental Technology, and the Association of Analytical Chemists in Official Methods of Analysis of AOAC International, 16th Edition. EPA has concluded that these methods have the necessary sensitivity and specificity to meet the data quality objectives of the LT2ESWTR.

The Agency conducted a search to identify potentially applicable voluntary consensus standards for analysis of Cryptosporidium. However, we identified no such standards. Therefore,

EPA approves the use of the following methods for Cryptosporidium analysis: Method 1623: Cryptosporidium and Giardia in Water by Filtration/IMS/FA, 2004, United States Environmental Protection Agency, EPA–815–R–05–002 or Method 1622: Cryptosporidium in Water by Filtration/IMS/FA, 2004, United States Environmental Protection Agency, EPA–815–R–05–001.

J. Executive Order 12898: Federal Actions To Address Environmental Justice in Minority Populations or Low-Income Populations

Executive Order 12898 establishes a Federal policy for incorporating environmental justice into Federal agency missions by directing agencies to identify and address disproportionately high and adverse human health or environmental effects of its programs, policies, and activities on minority and low-income populations. EPA has considered environmental justice related issues concerning the potential impacts of this action and consulted with minority and low-income stakeholders. A description of this consultation can be found in the proposed rule (USEPA 2003a).

K. Consultations With the Science Advisory Board, National Drinking Water Advisory Council, and the Secretary of Health and Human Services

In accordance with Section 1412 (d) and (e) of the SDWA, the Agency did consult with the Science Advisory Board, the National Drinking Water Advisory Council (NDWAC), and the Secretary of Health and Human Services on today's rule.

EPA charged the SAB panel with reviewing the following aspects of the LT2ESWTR proposal:

- The analysis of Cryptosporidium occurrence;
- The pre- and post-LT2ESWTR Cryptosporidium risk assessment; and
- The treatment credits for the following four microbial toolbox components: raw water off-stream storage, pre-sedimentation, lime softening, and lower finished water turbidity.

EPA met with the SAB to discuss the LT2ESWTR on June 13, 2001 (Washington, DC), September 25–26, 2001 (teleconference), and December 10–12, 2001 (Los Angeles, CA). The SAB issued its final report for this review, Disinfection Byproducts and Surface Water Treatment: A EPA Science Advisory Board Review of Certain Elements of the Stage 2 Regulatory Proposals, in May 2003.

Comments from the SAB were generally supportive of EPA's analysis of Cryptosporidium occurrence and the Cryptosporidium risk assessment for today's rule. The SAB recommended some additional quality assurance checks for statistical models, improved descriptions of underlying data sets, and better characterization of uncertainty for key parameters. USEPA 2005a and 2005b provide information on revisions EPA made in response to these comments.

SAB comments on microbial toolbox options and the Agency's responses to those comments are described in section IIII.D of this preamble. In general, the SAB supported treatment credit for two-stage softening, recommended additional performance criteria to award treatment credit to presedimentation basins, recommended modifications to the treatment credit for combined and individual filter performance, and opposed treatment credit for off-stream raw water storage.

EPA met with the NDWAC on November 8, 2001, in Washington, DC, to discuss the LT2ESWTR proposal. EPA specifically requested comments from the NDWAC on the regulatory approach taken in the proposed microbial toolbox (e.g., proposal of specific design and implementation criteria for treatment credits). The Council was generally supportive of EPA establishing criteria for awarding treatment credit to toolbox components, but recommended that EPA provide flexibility for States to address PWS specific situations. EPA believes that the demonstration of performance credit, described in section IV.D.9 provides this flexibility by allowing States to award higher or lower levels of treatment credit for microbial toolbox components based on site specific conditions.

EPA has consulted with the U.S. Department of Health and Human Services (HHS) regarding Cryptosporidium health effects and has provided HHS with today's rule.

L. Plain Language

Executive Order 12866 requires each agency to write its rules in plain language. Readable regulations help the public find requirements quickly and understand them easily. They increase compliance, strengthen enforcement, and decrease mistakes, frustration, phone calls, appeals, and distrust of government. EPA made every effort to write this preamble to the final rule in as clear, concise, and unambiguous manner as possible.

M. Analysis of the Likely Effect of Compliance With the LT2ESWTR on the Technical, Financial, and Managerial Capacity of Public Water Systems

Section 1420(d)(3) of SDWA, as amended, requires that in promulgating an NPDWR, the Administrator shall include an analysis of the likely effect of compliance with the regulation on the technical, managerial, and financial capacity of public water systems. This analysis can be found in the LT2ESWTR Economic Analysis (USEPA 2005a). Analyses reflect only the impact of new or revised requirements, as established by the LT2ESWTR; the impacts of previously established requirements on system capacity are not considered.

EPA has defined overall water system capacity as the ability to plan for, achieve, and maintain compliance with applicable drinking water standards. Capacity encompasses three components: technical, managerial, and financial. Technical capacity is the physical and operational ability of a water system to meet SDWA requirements. This refers to the physical infrastructure of the water system, including the adequacy of source water and the adequacy of treatment, storage, and distribution infrastructure. It also refers to the ability of system personnel to adequately operate and maintain the system and to otherwise implement requisite technical knowledge. Managerial capacity is the ability of a water system to conduct its affairs to achieve and maintain compliance with SDWA requirements. Managerial capacity refers to the system's institutional and administrative capabilities. Financial capacity is a water system's ability to acquire and manage sufficient financial resources to allow the system to achieve and maintain compliance with SDWA requirements. Technical, managerial, and financial capacity can be assessed through key issues and questions, including the following:

Technical Capacity	
Source water adequacy	Does the system have a reliable source of water with adequate quantity? Is the source generally of good quality and adequately protected?

Infrastructure adequacy	Can the system provide water that meets SDWA standards? What is the condition of its infrastructure, including wells or source water intakes, treatment and storage facilities, and distribution systems? What is the infrastructure's life expectancy? Does the system have a capital improvement plan?
Technical knowledge and implementation.	Are the system's operators certified? Do the operators have sufficient knowledge of applicable standards? Can the operators effectively implement this technical knowledge? Do the operators understand the system's technical and operational characteristics? Does the system have an effective O&M program?
Managerial Capacity	
Ownership accountability	Are the owners clearly identified? Can they be held accountable for the system?
Staffing and organization	Are the operators and managers clearly identified? Is the system properly organized and staffed? Do personnel understand the management aspects of regulatory requirements and system operations? Do they have adequate expertise to manage water system operations (i.e., to conduct implementation, monitor for E. coli and Cryptosporidium, install treatment, and cover or disinfect reservoir discharge to meet the LT2ESWTR requirements)? Do personnel have the necessary licenses and certifications?
Effective external linkages	Does the system interact well with customers, regulators, and other entities? Is the system aware of available external resources, such as technical and financial assistance?
Financial Capacity	
Revenue sufficiency	Do revenues cover costs?
Creditworthiness	Is the system financially healthy? Does it have access to capital through public or private sources?
Fiscal management and controls	Are adequate books and records maintained? Are appropriate budgeting, accounting, and financial planning methods used? Does the system manage its revenues effectively?

After determining the type and number of systems to which each requirement applies, EPA evaluated the capacity impact of each rule requirement on large and small systems affected by that particular requirement. EPA determined that the overall impacts on small systems' technical, managerial, and financial capacity will vary. Monitoring and familiarization with new rules will have no significant effects on small systems, with the exception of moderate revenue constraints on those systems that need to implement monitoring for Cryptosporidium. The largest impacts will occur as a result of attaining 2.5 log treatment levels, covering uncovered reservoirs, or disinfecting reservoir discharge. EPA assumed that large systems will have the technical, financial, and managerial capacity to implement LT2ESWTR requirements based on the scale and complexity of their operations. The nature of their operations generally assures that they have access to the technical and managerial expertise to carry out all activities required by the LT2ESWTR. It is also generally easier for large systems to fund capital improvements than small systems, since costs can be spread over a larger customer base, making them smaller on a per-household basis.

To meet challenges posed by rule requirements, it is likely that some small and medium systems will need to develop or enhance linkages with technical and financial assistance providers (including State extension agents). Technical and financial assistance providers can help systems analyze their needs as well as the trade-offs between cost and health protection. In addition, they may be able to assist systems in finding the funding necessary to install and operate new equipment. The Safe Drinking Water Act, as amended in 1996, established the Drinking Water State Revolving Fund to make funds available to drinking water systems to finance infrastructure improvements. EPA also works closely with organizations such as the National Rural Water Association and the American Water Works Association to develop technical and managerial tools, materials, and assistance to aid small systems.

N. Congressional Review Act

The Congressional Review Act, 5 U.S.C. 801 et seq., as added by the Small Business Regulatory Enforcement Fairness Act of 1996, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report, which includes a copy of the rule, to each House of the Congress and to the Comptroller General of the United States. EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of the rule in the **Federal Register**. A Major rule cannot take effect until 60 days after it is published in the **Federal Register**. This action is a ''major rule'' as defined by 5 U.S.C. 804(2). This rule will be effective March 6, 2006.

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List of Subjects

40 CFR Part 9

Reporting and recordkeeping.

40 CFR Part 141

Environmental protection, Chemicals, Indians-lands, Incorporation by reference, Intergovernmental relations, Radiation protection, Reporting and recordkeeping requirements, Water supply.

40 CFR Part 142

Environmental protection, Administrative practice and procedure, Chemicals, Indians-lands, Radiation protection, Reporting and recordkeeping requirements, Water supply.

Dated: December 15, 2005.

Stephen L. Johnson,

Administrator.

■ For the reasons set forth in the preamble, title 40 chapter I of the Code of Federal Regulations is amended as follows:

PART 9—[AMENDED]

■ 1. The authority citation for part 9 continues to read as follows:

Authority: 7 U.S.C. 135 *et seq.*, 136–136y; 15 U.S.C. 2001, 2003, 2005, 2006, 2601–2671; 21 U.S.C. 331j, 346a, 348; 31 U.S.C. 9701; 33 U.S.C. 1251 *et seq.*, 1311, 1313d, 1314, 1318, 1321, 1326, 1330, 1342, 1344, 1345 (d) and (e), 1361; Executive Order 11735, 38 FR 21243, 3 CFR, 1971–1975 Comp. p. 973; 42 U.S.C. 241, 242b, 243, 246, 300f, 300g, 300g–1, 300g–2, 300g–3, 300g–4, 300g–5, 300g–6, 300j–1, 300j–2, 300j–3, 300j–4, 300j–9, 1857 *et seq.*, 6901–6992k, 7401–7671q, 7542, 9601–9657, 11023, 11048.

■ 2. In § 9.1 the table is amended as follows:

■ a. Under the heading ''National Primary Drinking Water Regulations Implementation'' by adding entries in numerical order for ''§ 141.706–141.710, 141.713–141.714, 141.716–141.723''.

■ b. Under the heading ''National Primary Drinking Water Regulations Implementation'' by removing entries § 142.15(c), 142.15(c)(6)–(7) and adding entries in numerical order for ''142.14(a)(9), 142.15(c)(6), and 142.16(n)'' as follows:

§ 9.1 OMB approvals under the Paperwork Reduction Act.

* * * * *

40 CFR citation	OMB control No.
* * * * * * *	
National Primary Drinking Water Regulations	
* * * * * * *	
141.706–141.710	2040–0266
141.713–141.714	2040–0266
141.716–141.723	2040–0266
National Primary Drinking Water Regulations Implementation	
* * * * * * *	
142.14(a)(9)	2040–0266
* * * * * * *	
142.15(c)(6)	2040–0266
* * * * * * *	
142.16(n)	2040–0266
* * * * * * *	

PART 141—NATIONAL PRIMARY DRINKING WATER REGULATIONS

■ 3. The authority citation for Part 141 continues to read as follows:

Authority: 42 U.S.C. 300f, 300g–1, 300g–2, 300g–3, 300g–4, 300g–5, 300g–6, 300j–4, 300j–9, and 300j–11.

■ 4. Section 141.2 is amended by adding, in alphabetical order, definitions for ''Bag filters'', ''Bank filtration'', ''Cartridge filters'', ''Flowing stream'', ''Lake/reservoir'', ''Membrane filtration'', ''Plant intake'', ''Presedimentation'', and ''Two-stage lime softening'', and revising the definition for ''Uncovered finished water storage facility'' to read as follows:

§ 141.2 Definitions.

* * * * *

Bag filters are pressure-driven separation devices that remove particulate matter larger than 1 micrometer using an engineered porous filtration media. They are typically constructed of a non-rigid, fabric filtration media housed in a pressure vessel in which the direction of flow is from the inside of the bag to outside.

Bank filtration is a water treatment process that uses a well to recover surface water that has naturally infiltrated into ground water through a river bed or bank(s). Infiltration is typically enhanced by the hydraulic gradient imposed by a nearby pumping water supply or other well(s).

* * * * *

Cartridge filters are pressure-driven separation devices that remove particulate matter larger than 1 micrometer using an engineered porous filtration media. They are typically constructed as rigid or semi-rigid, self-supporting filter elements housed in pressure vessels in which flow is from the outside of the cartridge to the inside.

* * * * *

Flowing stream is a course of running water flowing in a definite channel.

* * * * *

Lake/reservoir refers to a natural or man made basin or hollow on the Earth's surface in which water collects or is stored that may or may not have a current or single direction of flow.

* * * * *

Membrane filtration is a pressure or vacuum driven separation process in which particulate matter larger than 1 micrometer is rejected by an engineered barrier, primarily through a size-exclusion mechanism, and which has a measurable removal efficiency of a target organism that can be verified through the application of a direct integrity test. This definition includes the common membrane technologies of microfiltration, ultrafiltration, nanofiltration, and reverse osmosis.

* * * * *

Plant intake refers to the works or structures at the head of a conduit through which water is diverted from a source (e.g., river or lake) into the treatment plant.

* * * * *

Presedimentation is a preliminary treatment process used to remove gravel, sand and other particulate material from the source water through settling before the water enters the primary clarification and filtration processes in a treatment plant.

* * * * *

Two-stage lime softening is a process in which chemical addition and hardness precipitation occur in each of two distinct unit clarification processes in series prior to filtration.

Uncovered finished water storage facility is a tank, reservoir, or other facility used to store water that will undergo no further treatment to reduce microbial pathogens except residual disinfection and is directly open to the atmosphere.

* * * * *

■ 5. Subpart Q of part 141 is amended by adding § 141.211 to read as follows:

§ 141.211 Special notice for repeated failure to conduct monitoring of the source water for *Cryptosporidium* and for failure to determine bin classification or mean *Cryptosporidium* level.

(a) *When is the special notice for repeated failure to monitor to be given?* The owner or operator of a community or non-community water system that is required to monitor source water under § 141.701 must notify persons served by the water system that monitoring has not been completed as specified no later than 30 days after the system has failed to collect any 3 months of monitoring as specified in § 141.701(c). The notice must be repeated as specified in § 141.203(b).

(b) *When is the special notice for failure to determine bin classification or mean* Cryptosporidium *level to be given?* The owner or operator of a community or non-community water system that is required to determine a bin classification under § 141.710, or to determine mean *Cryptosporidium* level under § 141.712, must notify persons served by the water system that the determination has not been made as required no later than 30 days after the system has failed report the determination as specified in § 141.710(e) or § 141.712(a), respectively. The notice must be repeated as specified in § 141.203(b). The notice is not required if the system is complying with a State-approved schedule to address the violation.

(c) *What is the form and manner of the special notice?* The form and manner of the public notice must follow the requirements for a Tier 2 public notice prescribed in § 141.203(c). The public notice must be presented as required in § 141.205(c).

(d) *What mandatory language must be contained in the special notice?* The notice must contain the following language, including the language necessary to fill in the blanks.

(1) The special notice for repeated failure to conduct monitoring must contain the following language:

> We are required to monitor the source of your drinking water for *Cryptosporidium*. Results of the monitoring are to be used to determine whether water treatment at the (treatment plant name) is sufficient to adequately remove *Cryptosporidium* from your drinking water. We are required to complete this monitoring and make this determination by (required bin determination date). We ''did not monitor or test'' or ''did not complete all monitoring or testing'' on schedule and, therefore, we may not be able to determine by the required date what treatment modifications, if any, must be made to ensure adequate *Cryptosporidium* removal. Missing this deadline may, in turn, jeopardize our ability to have the required treatment modifications, if any, completed by the deadline required, (date).
>
> For more information, please call (name of water system contact) of (name of water system) at (phone number).

(2) The special notice for failure to determine bin classification or mean Cryptosporidium level must contain the following language:

> We are required to monitor the source of your drinking water for Cryptosporidium in order to determine by (date) whether water treatment at the (treatment plant name) is sufficient to adequately remove Cryptosporidium from your drinking water. We have not made this determination by the required date. Our failure to do this may jeopardize our ability to have the required treatment modifications, if any, completed by the required deadline of (date). For more information, please call (name of water system contact) of (name of water system) at (phone number).

(3) Each special notice must also include a description of what the system is doing to correct the violation and when the system expects to return to compliance or resolve the situation.

■ 6. Appendix A to Subpart Q of part 141 is amended by adding entry number 10 under I.A. to read as follows:

Subpart Q—Public Notification of Drinking Water Violations

APPENDIX A TO SUBPART Q OF PART 141—NPDWR VIOLATIONS AND OTHER SITUATIONS REQUIRING PUBLIC NOTICE [1]

Contaminant	MCL/MRDL/TT violations [2]		Monitoring & testing procedure violations	
	Tier of public notice required	Citation	Tier of public notice required	Citation
I. Violations of National Primary Drinking Water Regulations (NPDWR): [3]				
A. Microbiological Contaminants				
* * *	*	*	*	* *
10. LT2ESWTR violations	2	141.710–141.720	[22] 2, 3	141.701–141.705 and 141.708–141.709.
* * *	*	*	*	* *

[1] Violations and other situations not listed in this table (e.g., failure to prepare Consumer Confidence Reports) do not require notice, unless otherwise determined by the primary agency. Primacy agencies may, at their option, also require a more stringent public notice tier (e.g., Tier 1 instead of Tier 2 or Tier 2 instead of Tier 3) for specific violations and situations listed in this Appendix, as authorized under § 141.202(a) and § 141.203(a).

[2] MCL—Maximum contaminant level, MRDL—Maximum residual disinfectant level, TT—Treatment technique.

[3] The term Violations of National Primary Drinking Water Regulations (NPDWR) is used here to include violations of MCL, MRDL, treatment technique, monitoring, and testing procedure requirements.

* * * * * * *

[22] Failure to collect three or more samples for Cryptosporidium analysis is a Tier 2 violation requiring special notice as specified in § 141.211. All other monitoring and testing procedure violations are Tier 3.

■ 7. Part 141 is amended by adding a new subpart W to read as follows:

Subpart W—Enhanced Treatment for *Cryptosporidium*

General Requirements

Sec.
141.700 General requirements.

Source Water Monitoring Requirements

141.701 Source water monitoring.
141.702 Sampling schedules.
141.703 Sampling locations.
141.704 Analytical methods.
141.705 Approved laboratories.
141.706 Reporting source water monitoring results.
141.707 Grandfathering previously collected data.

Disinfection Profiling and Benchmarking Requirements

141.708 Requirements when making a significant change in disinfection practice.
141.709 Developing the disinfection profile and benchmark.

Treatment Technique Requirements

141.710 Bin classification for filtered systems.
141.711 Filtered system additional *Cryptosporidium* treatment requirements.
141.712 Unfiltered system *Cryptosporidium* treatment requirements.
141.713 Schedule for compliance with *Cryptosporidium* treatment requirements.
141.714 Requirements for uncovered finished water storage facilities.

Requirements for Microbial Toolbox Components

141.715 Microbial toolbox options for meeting *Cryptosporidium* treatment requirements.
141.716 Source toolbox components.
141.717 Pre-filtration treatment toolbox components.
141.718 Treatment performance toolbox components.
141.719 Additional filtration toolbox components.
141.720 Inactivation toolbox components.

Reporting and Recordkeeping Requirements

141.721 Reporting requirements.
141.722 Recordkeeping requirements.

Requirements for Sanitary Surveys Performed by EPA

141.723 Requirements to respond to significant deficiencies identified in sanitary surveys performed by EPA.

Subpart W—Enhanced Treatment for *Cryptosporidium*

General Requirements

§ 141.700 General requirements.

(a) The requirements of this subpart W are national primary drinking water regulations. The regulations in this subpart establish or extend treatment technique requirements in lieu of maximum contaminant levels for *Cryptosporidium.* These requirements are in addition to requirements for filtration and disinfection in subparts H, P, and T of this part.

(b) *Applicability.* The requirements of this subpart apply to all subpart H systems, which are public water systems supplied by a surface water source and public water systems supplied by a ground water source under the direct influence of surface water.

(1) Wholesale systems, as defined in § 141.2, must comply with the requirements of this subpart based on the population of the largest system in the combined distribution system.

(2) The requirements of this subpart for filtered systems apply to systems required by National Primary Drinking Water Regulations to provide filtration treatment, whether or not the system is currently operating a filtration system.

(3) The requirements of this subpart for unfiltered systems apply only to unfiltered systems that timely met and continue to meet the filtration avoidance criteria in subparts H, P, and T of this part, as applicable.

(c) *Requirements.* Systems subject to this subpart must comply with the following requirements:

(1) Systems must conduct an initial and a second round of source water monitoring for each plant that treats a surface water or GWUDI source. This monitoring may include sampling for *Cryptosporidium, E. coli,* and turbidity as described in §§ 141.701 through 141.706, to determine what level, if any, of additional *Cryptosporidium* treatment they must provide.

(2) Systems that plan to make a significant change to their disinfection practice must develop disinfection profiles and calculate disinfection benchmarks, as described in §§ 141.708 through 141.709.

(3) Filtered systems must determine their *Cryptosporidium* treatment bin classification as described in § 141.710 and provide additional treatment for *Cryptosporidium,* if required, as described in § 141.711. All unfiltered systems must provide treatment for *Cryptosporidium* as described in § 141.712. Filtered and unfiltered systems must implement *Cryptosporidium* treatment according to the schedule in § 141.713.

(4) Systems with uncovered finished water storage facilities must comply with the requirements to cover the facility or treat the discharge from the facility as described in § 141.714.

(5) Systems required to provide additional treatment for *Cryptosporidium* must implement microbial toolbox options that are designed and operated as described in §§ 141.715 through 141.720.

(6) Systems must comply with the applicable recordkeeping and reporting requirements described in §§ 141.721 through 141.722.

(7) Systems must address significant deficiencies identified in sanitary surveys performed by EPA as described in § 141.723.

Source Water Monitoring Requirements

§ 141.701 Source water monitoring.

(a) *Initial round of source water monitoring.* Systems must conduct the following monitoring on the schedule in paragraph (c) of this section unless they meet the monitoring exemption criteria in paragraph (d) of this section.

(1) Filtered systems serving at least 10,000 people must sample their source water for *Cryptosporidium, E. coli,* and turbidity at least monthly for 24 months.

(2) Unfiltered systems serving at least 10,000 people must sample their source water for *Cryptosporidium* at least monthly for 24 months.

(3)(i) Filtered systems serving fewer than 10,000 people must sample their source water for *E. coli* at least once every two weeks for 12 months.

(ii) A filtered system serving fewer than 10,000 people may avoid *E. coli* monitoring if the system notifies the State that it will monitor for *Cryptosporidium* as described in paragraph (a)(4) of this section. The system must notify the State no later than 3 months prior to the date the system is otherwise required to start *E. coli* monitoring under § 141.701(c).

(4) Filtered systems serving fewer than 10,000 people must sample their source water for *Cryptosporidium* at least twice per month for 12 months or at least monthly for 24 months if they meet one of the following, based on monitoring conducted under paragraph (a)(3) of this section:

(i) For systems using lake/reservoir sources, the annual mean *E. coli* concentration is greater than 10 *E. coli*/100 mL.

(ii) For systems using flowing stream sources, the annual mean *E. coli* concentration is greater than 50 *E. coli*/100 mL.

(iii) The system does not conduct *E. coli* monitoring as described in paragraph (a)(3) of this section.

(iv) Systems using ground water under the direct influence of surface water (GWUDI) must comply with the requirements of paragraph (a)(4) of this section based on the *E. coli* level that applies to the nearest surface water body. If no surface water body is nearby, the system must comply based on the requirements that apply to systems using lake/reservoir sources.

(5) For filtered systems serving fewer than 10,000 people, the State may approve monitoring for an indicator other than *E. coli* under paragraph (a)(3) of this section. The State also may approve an alternative to the *E. coli* concentration in paragraph (a)(4)(i), (ii) or (iv) of this section to trigger *Cryptosporidium* monitoring. This approval by the State must be provided to the system in writing and must include the basis for the State's determination that the alternative indicator and/or trigger level will provide a more accurate identification of whether a system will exceed the Bin 1 *Cryptosporidium* level in § 141.710.

(6) Unfiltered systems serving fewer than 10,000 people must sample their source water for *Cryptosporidium* at least twice per month for 12 months or at least monthly for 24 months.

(7) Systems may sample more frequently than required under this section if the sampling frequency is evenly spaced throughout the monitoring period.

(b) *Second round of source water monitoring.* Systems must conduct a second round of source water monitoring that meets the requirements for monitoring parameters, frequency, and duration described in paragraph (a) of this section, unless they meet the monitoring exemption criteria in paragraph (d) of this section. Systems must conduct this monitoring on the schedule in paragraph (c) of this section.

(c) *Monitoring schedule.* Systems must begin the monitoring required in paragraphs (a) and (b) of this section no later than the month beginning with the date listed in this table:

SOURCE WATER MONITORING STARTING DATES TABLE

Systems that serve . . .	Must begin the first round of source water monitoring no later than the month beginning . . .	And must begin the second round of source water monitoring no later than the month beginning . . .
(1) At least 100,000 people	(i) October 1, 2006	(ii) April 1, 2015.
(2) From 50,000 to 99,999 people	(i) April 1, 2007	(ii) October 1, 2015.
(3) From 10,000 to 49,999 people	(i) April 1, 2008	(ii) October 1, 2016.
(4) Fewer than 10,000 and monitor for *E. coli*[a]	(i) October 1, 2008	(ii) October 1, 2017.
(5) Fewer than 10,000 and monitor for *Cryptosporidium*[b].	(i) April 1, 2010	(ii) April 1, 2019.

[a] Applies only to filtered systems.
[b] Applies to filtered systems that meet the conditions of paragraph (a)(4) of this section and unfiltered systems.

(d) *Monitoring avoidance.* (1) Filtered systems are not required to conduct source water monitoring under this subpart if the system will provide a total of at least 5.5-log of treatment for *Cryptosporidium,* equivalent to meeting the treatment requirements of Bin 4 in § 141.711.

(2) Unfiltered systems are not required to conduct source water monitoring under this subpart if the system will provide a total of at least 3-log *Cryptosporidium* inactivation, equivalent to meeting the treatment requirements for unfiltered systems with a mean *Cryptosporidium* concentration of greater than 0.01 oocysts/L in § 141.712.

(3) If a system chooses to provide the level of treatment in paragraph (d)(1) or (2) of this section, as applicable, rather than start source water monitoring, the system must notify the State in writing no later than the date the system is otherwise required to submit a sampling schedule for monitoring under § 141.702. Alternatively, a system may choose to stop sampling at any point after it has initiated monitoring if it notifies the State in writing that it will provide this level of treatment. Systems must install and operate technologies to provide this level of treatment by the

applicable treatment compliance date in § 141.713.

(e) *Plants operating only part of the year.* Systems with subpart H plants that operate for only part of the year must conduct source water monitoring in accordance with this subpart, but with the following modifications:

(1) Systems must sample their source water only during the months that the plant operates unless the State specifies another monitoring period based on plant operating practices.

(2) Systems with plants that operate less than six months per year and that monitor for *Cryptosporidium* must collect at least six *Cryptosporidium* samples per year during each of two years of monitoring. Samples must be evenly spaced throughout the period the plant operates.

(f)(1) *New sources.* A system that begins using a new source of surface water or GWUDI after the system is required to begin monitoring under paragraph (c) of this section must monitor the new source on a schedule the State approves. Source water monitoring must meet the requirements of this subpart. The system must also meet the bin classification and *Cryptosporidium* treatment requirements of §§ 141.710 and 141.711 or § 141.712, as applicable, for the new source on a schedule the State approves.

(2) The requirements of § 141.701(f) apply to subpart H systems that begin operation after the monitoring start date applicable to the system's size under paragraph (c) of this section.

(3) The system must begin a second round of source water monitoring no later than 6 years following initial bin classification under § 141.710 or determination of the mean *Cryptosporidium* level under § 141.712, as applicable.

(g) Failure to collect any source water sample required under this section in accordance with the sampling schedule, sampling location, analytical method, approved laboratory, and reporting requirements of §§ 141.702 through 141.706 is a monitoring violation.

(h) *Grandfathering monitoring data.* Systems may use (grandfather) monitoring data collected prior to the applicable monitoring start date in paragraph (c) of this section to meet the initial source water monitoring requirements in paragraph (a) of this section. Grandfathered data may substitute for an equivalent number of months at the end of the monitoring period. All data submitted under this paragraph must meet the requirements in § 141.707.

§ 141.702 Sampling schedules.

(a) Systems required to conduct source water monitoring under § 141.701 must submit a sampling schedule that specifies the calendar dates when the system will collect each required sample.

(1) Systems must submit sampling schedules no later than 3 months prior to the applicable date listed in § 141.701(c) for each round of required monitoring.

(2)(i) Systems serving at least 10,000 people must submit their sampling schedule for the initial round of source water monitoring under § 141.701(a) to EPA electronically at *https://intranet.epa.gov/lt2/.*

(ii) If a system is unable to submit the sampling schedule electronically, the system may use an alternative approach for submitting the sampling schedule that EPA approves.

(3) Systems serving fewer than 10,000 people must submit their sampling schedules for the initial round of source water monitoring § 141.701(a) to the State.

(4) Systems must submit sampling schedules for the second round of source water monitoring § 141.701(b) to the State.

(5) If EPA or the State does not respond to a system regarding its sampling schedule, the system must sample at the reported schedule.

(b) Systems must collect samples within two days before or two days after the dates indicated in their sampling schedule (i.e., within a five-day period around the schedule date) unless one of the conditions of paragraph (b)(1) or (2) of this section applies.

(1) If an extreme condition or situation exists that may pose danger to the sample collector, or that cannot be avoided and causes the system to be unable to sample in the scheduled five-day period, the system must sample as close to the scheduled date as is feasible unless the State approves an alternative sampling date. The system must submit an explanation for the delayed sampling date to the State concurrent with the shipment of the sample to the laboratory.

(2)(i) If a system is unable to report a valid analytical result for a scheduled sampling date due to equipment failure, loss of or damage to the sample, failure to comply with the analytical method requirements, including the quality control requirements in § 141.704, or the failure of an approved laboratory to analyze the sample, then the system must collect a replacement sample.

(ii) The system must collect the replacement sample not later than 21 days after receiving information that an analytical result cannot be reported for the scheduled date unless the system demonstrates that collecting a replacement sample within this time frame is not feasible or the State approves an alternative resampling date. The system must submit an explanation for the delayed sampling date to the State concurrent with the shipment of the sample to the laboratory.

(c) Systems that fail to meet the criteria of paragraph (b) of this section for any source water sample required under § 141.701 must revise their sampling schedules to add dates for collecting all missed samples. Systems must submit the revised schedule to the State for approval prior to when the system begins collecting the missed samples.

§ 141.703 Sampling locations.

(a) Systems required to conduct source water monitoring under § 141.701 must collect samples for each plant that treats a surface water or GWUDI source. Where multiple plants draw water from the same influent, such as the same pipe or intake, the State may approve one set of monitoring results to be used to satisfy the requirements of § 141.701 for all plants.

(b)(1) Systems must collect source water samples prior to chemical treatment, such as coagulants, oxidants and disinfectants, unless the system meets the condition of paragraph (b)(2) of this section.

(2) The State may approve a system to collect a source water sample after chemical treatment. To grant this approval, the State must determine that collecting a sample prior to chemical treatment is not feasible for the system and that the chemical treatment is unlikely to have a significant adverse effect on the analysis of the sample.

(c) Systems that recycle filter backwash water must collect source water samples prior to the point of filter backwash water addition.

(d) *Bank filtration.* (1) Systems that receive *Cryptosporidium* treatment credit for bank filtration under § 141.173(b) or § 141.552(a), as applicable, must collect source water samples in the surface water prior to bank filtration.

(2) Systems that use bank filtration as pretreatment to a filtration plant must collect source water samples from the well (i.e., after bank filtration). Use of bank filtration during monitoring must be consistent with routine operational practice. Systems collecting samples after a bank filtration process may not receive treatment credit for the bank filtration under § 141.717(c).

(e) *Multiple sources.* Systems with plants that use multiple water sources, including multiple surface water sources and blended surface water and ground water sources, must collect samples as specified in paragraph (e)(1) or (2) of this section. The use of multiple sources during monitoring must be consistent with routine operational practice.

(1) If a sampling tap is available where the sources are combined prior to treatment, systems must collect samples from the tap.

(2) If a sampling tap where the sources are combined prior to treatment is not available, systems must collect samples at each source near the intake on the same day and must follow either paragraph (e)(2)(i) or (ii) of this section for sample analysis.

(i) Systems may composite samples from each source into one sample prior to analysis. The volume of sample from each source must be weighted according to the proportion of the source in the total plant flow at the time the sample is collected.

(ii) Systems may analyze samples from each source separately and calculate a weighted average of the analysis results for each sampling date. The weighted average must be calculated by multiplying the analysis result for each source by the fraction the source contributed to total plant flow at the time the sample was collected and then summing these values.

(f) *Additional Requirements.* Systems must submit a description of their sampling location(s) to the State at the same time as the sampling schedule required under § 141.702. This description must address the position of the sampling location in relation to the system's water source(s) and treatment processes, including pretreatment, points of chemical treatment, and filter backwash recycle. If the State does not respond to a system regarding sampling location(s), the system must sample at the reported location(s).

§ 141.704 Analytical methods.

(a) *Cryptosporidium.* Systems must analyze for *Cryptosporidium* using *Method 1623: Cryptosporidium and Giardia in Water by Filtration/IMS/FA,* 2005, United States Environmental Protection Agency, EPA–815-R–05–002 or *Method 1622: Cryptosporidium in Water by Filtration/IMS/FA,* 2005, United States Environmental Protection Agency, EPA–815–R–05–001, which are incorporated by reference. The Director of the Federal Register approves this incorporation by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. You may obtain a copy of these methods online from *http://www.epa.gov/safewater/disinfection/lt2* or from the United States Environmental Protection Agency, Office of Ground Water and Drinking Water, 1201 Constitution Ave., NW, Washington, DC 20460 (Telephone: 800–426–4791). You may inspect a copy at the Water Docket in the EPA Docket Center, 1301 Constitution Ave., NW, Washington, DC, (Telephone: 202–566–2426) or at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to: h*ttp://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html.*

(1) Systems must analyze at least a 10 L sample or a packed pellet volume of at least 2 mL as generated by the methods listed in paragraph (a) of this section. Systems unable to process a 10 L sample must analyze as much sample volume as can be filtered by two filters approved by EPA for the methods listed in paragraph (a) of this section, up to a packed pellet volume of at least 2 mL.

(2)(i) Matrix spike (MS) samples, as required by the methods in paragraph (a) of this section, must be spiked and filtered by a laboratory approved for *Cryptosporidium* analysis under § 141.705.

(ii) If the volume of the MS sample is greater than 10 L, the system may filter all but 10 L of the MS sample in the field, and ship the filtered sample and the remaining 10 L of source water to the laboratory. In this case, the laboratory must spike the remaining 10 L of water and filter it through the filter used to collect the balance of the sample in the field.

(3) Flow cytometer-counted spiking suspensions must be used for MS samples and ongoing precision and recovery (OPR) samples.

(b) *E. coli.* Systems must use methods for enumeration of E. coli in source water approved in § 136.3(a) of this title.

(1) The time from sample collection to initiation of analysis may not exceed 30 hours unless the system meets the condition of paragraph (b)(2) of this section.

(2) The State may approve on a case-by-case basis the holding of an *E. coli* sample for up to 48 hours between sample collection and initiation of analysis if the State determines that analyzing an *E. coli* sample within 30 hours is not feasible. *E. coli* samples held between 30 to 48 hours must be analyzed by the Colilert reagent version of Standard Method 9223B as listed in § 136.3(a) of this title.

(3) Systems must maintain samples between 0°C and 10°C during storage and transit to the laboratory.

(c) *Turbidity.* Systems must use methods for turbidity measurement approved in § 141.74(a)(1).

§ 141.705 Approved laboratories.

(a) *Cryptosporidium.* Systems must have *Cryptosporidium* samples analyzed by a laboratory that is approved under EPA's Laboratory Quality Assurance Evaluation Program for Analysis of *Cryptosporidium* in Water or a laboratory that has been certified for *Cryptosporidium* analysis by an equivalent State laboratory certification program.

(b) *E. coli.* Any laboratory certified by the EPA, the National Environmental Laboratory Accreditation Conference or the State for total coliform or fecal coliform analysis under § 141.74 is approved for *E. coli* analysis under this subpart when the laboratory uses the same technique for *E. coli* that the laboratory uses for § 141.74.

(c) *Turbidity.* Measurements of turbidity must be made by a party approved by the State.

§ 141.706 Reporting source water monitoring results.

(a) Systems must report results from the source water monitoring required under § 141.701 no later than 10 days after the end of the first month following the month when the sample is collected.

(b)(1) All systems serving at least 10,000 people must report the results from the initial source water monitoring required under § 141.701(a) to EPA electronically at *https://intranet.epa.gov/lt2/.*

(2) If a system is unable to report monitoring results electronically, the system may use an alternative approach for reporting monitoring results that EPA approves.

(c) Systems serving fewer than 10,000 people must report results from the initial source water monitoring required under § 141.701(a) to the State.

(d) All systems must report results from the second round of source water monitoring required under § 141.701(b) to the State.

(e) Systems must report the applicable information in paragraphs (e)(1) and (2) of this section for the source water monitoring required under § 141.701.

(1) Systems must report the following data elements for each *Cryptosporidium* analysis:

Data element.
1. PWS ID.
2. Facility ID.

Data element.
3. Sample collection date.
4. Sample type (field or matrix spike).
5. Sample volume filtered (L), to nearest ¼ L.
6. Was 100% of filtered volume examined.
7. Number of oocysts counted.

(i) For matrix spike samples, systems must also report the sample volume spiked and estimated number of oocysts spiked. These data are not required for field samples.

(ii) For samples in which less than 10 L is filtered or less than 100% of the sample volume is examined, systems must also report the number of filters used and the packed pellet volume.

(iii) For samples in which less than 100% of sample volume is examined, systems must also report the volume of resuspended concentrate and volume of this resuspension processed through immunomagnetic separation.

(2) Systems must report the following data elements for each *E. coli* analysis:

Data element.
1. PWS ID.
2. Facility ID.
3. Sample collection date.
4. Analytical method number.
5. Method type.
6. Source type (flowing stream, lake/reservoir, GWUDI).
7. *E. coli*/100 mL.
8. Turbidity.[1]

[1] Systems serving fewer than 10,000 people that are not required to monitor for turbidity under § 141.701 are not required to report turbidity with their *E. coli* results.

§ 141.707 Grandfathering previously collected data.

(a)(1) Systems may comply with the initial source water monitoring requirements of § 141.701(a) by grandfathering sample results collected before the system is required to begin monitoring (i.e., previously collected data). To be grandfathered, the sample results and analysis must meet the criteria in this section and the State must approve.

(2) A filtered system may grandfather *Cryptosporidium* samples to meet the requirements of § 141.701(a) when the system does not have corresponding *E. coli* and turbidity samples. A system that grandfathers *Cryptosporidium* samples without *E. coli* and turbidity samples is not required to collect *E. coli* and turbidity samples when the system completes the requirements for *Cryptosporidium* monitoring under § 141.701(a).

(b) *E. coli sample analysis.* The analysis of *E. coli* samples must meet the analytical method and approved laboratory requirements of §§ 141.704 through 141.705.

(c) *Cryptosporidium sample analysis.* The analysis of *Cryptosporidium* samples must meet the criteria in this paragraph.

(1) Laboratories analyzed *Cryptosporidium* samples using one of the analytical methods in paragraphs (c)(1)(i) through (vi) of this section, which are incorporated by reference. The Director of the Federal Register approves this incorporation by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. You may obtain a copy of these methods on-line from the United States Environmental Protection Agency, Office of Ground Water and Drinking Water, 1201 Constitution Ave, NW, Washington, DC 20460 (Telephone: 800–426–4791). You may inspect a copy at the Water Docket in the EPA Docket Center, 1301 Constitution Ave., NW, Washington, DC, (Telephone: 202–566–2426) or at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to: *http://www.archives.gov/federal_ register/code_of_federal_ regulations/ibr_locations.html.*

(i) *Method 1623: Cryptosporidium and Giardia in Water by Filtration/IMS/FA,* 2005, United States Environmental Protection Agency, EPA–815–R–05–002.

(ii) *Method 1622: Cryptosporidium in Water by Filtration/IMS/FA,* 2005, United States Environmental Protection Agency, EPA–815–R–05–001.

(iii) *Method 1623: Cryptosporidium and Giardia in Water by Filtration/IMS/FA,* 2001, United States Environmental Protection Agency, EPA–821–R–01–025.

(iv) *Method 1622: Cryptosporidium in Water by Filtration/IMS/FA,* 2001, United States Environmental Protection Agency, EPA–821–-R–01–026.

(v) *Method 1623: Cryptosporidium and Giardia in Water by Filtration/IMS/FA,* 1999, United States Environmental Protection Agency, EPA–821–R–99–006.

(vi) *Method 1622: Cryptosporidium in Water by Filtration/IMS/FA,* 1999, United States Environmental Protection Agency, EPA–821–R–99–001.

(2) For each *Cryptosporidium* sample, the laboratory analyzed at least 10 L of sample or at least 2 mL of packed pellet or as much volume as could be filtered by 2 filters that EPA approved for the methods listed in paragraph (c)(1) of this section.

(d) *Sampling location.* The sampling location must meet the conditions in § 141.703.

(e) *Sampling frequency. Cryptosporidium* samples were collected no less frequently than each calendar month on a regular schedule, beginning no earlier than January 1999. Sample collection intervals may vary for the conditions specified in § 141.702(b)(1) and (2) if the system provides documentation of the condition when reporting monitoring results.

(1) The State may approve grandfathering of previously collected data where there are time gaps in the sampling frequency if the system conducts additional monitoring the State specifies to ensure that the data used to comply with the initial source water monitoring requirements of § 141.701(a) are seasonally representative and unbiased.

(2) Systems may grandfather previously collected data where the sampling frequency within each month varied. If the *Cryptosporidium* sampling frequency varied, systems must follow the monthly averaging procedure in § 141.710(b)(5) or § 141.712(a)(3), as applicable, when calculating the bin classification for filtered systems or the mean *Cryptosporidium* concentration for unfiltered systems.

(f) *Reporting monitoring results for grandfathering.* Systems that request to grandfather previously collected monitoring results must report the following information by the applicable dates listed in this paragraph. Systems serving at least 10,000 people must report this information to EPA unless the State approves reporting to the State rather than EPA. Systems serving fewer than 10,000 people must report this information to the State.

(1) Systems must report that they intend to submit previously collected monitoring results for grandfathering. This report must specify the number of previously collected results the system will submit, the dates of the first and last sample, and whether a system will conduct additional source water monitoring to meet the requirements of § 141.701(a). Systems must report this information no later than the date the sampling schedule under § 141.702 is required.

(2) Systems must report previously collected monitoring results for grandfathering, along with the associated documentation listed in paragraphs (f)(2)(i) through (iv) of this section, no later than two months after the applicable date listed in § 141.701(c).

(i) For each sample result, systems must report the applicable data elements in § 141.706.

(ii) Systems must certify that the reported monitoring results include all results the system generated during the time period beginning with the first reported result and ending with the final reported result. This applies to samples that were collected from the

sampling location specified for source water monitoring under this subpart, not spiked, and analyzed using the laboratory's routine process for the analytical methods listed in this section.

(iii) Systems must certify that the samples were representative of a plant's source water(s) and the source water(s) have not changed. Systems must report a description of the sampling location(s), which must address the position of the sampling location in relation to the system's water source(s) and treatment processes, including points of chemical addition and filter backwash recycle.

(iv) For *Cryptosporidium* samples, the laboratory or laboratories that analyzed the samples must provide a letter certifying that the quality control criteria specified in the methods listed in paragraph (c)(1) of this section were met for each sample batch associated with the reported results. Alternatively, the laboratory may provide bench sheets and sample examination report forms for each field, matrix spike, IPR, OPR, and method blank sample associated with the reported results.

(g) If the State determines that a previously collected data set submitted for grandfathering was generated during source water conditions that were not normal for the system, such as a drought, the State may disapprove the data. Alternatively, the State may approve the previously collected data if the system reports additional source water monitoring data, as determined by the State, to ensure that the data set used under § 141.710 or § 141.712 represents average source water conditions for the system.

(h) If a system submits previously collected data that fully meet the number of samples required for initial source water monitoring under § 141.701(a) and some of the data are rejected due to not meeting the requirements of this section, systems must conduct additional monitoring to replace rejected data on a schedule the State approves. Systems are not required to begin this additional monitoring until two months after notification that data have been rejected and additional monitoring is necessary.

Disinfection Profiling and Benchmarking Requirements

§ 141.708 Requirements when making a significant change in disinfection practice.

(a) Following the completion of initial source water monitoring under § 141.701(a), a system that plans to make a significant change to its disinfection practice, as defined in paragraph (b) of this section, must develop disinfection profiles and calculate disinfection benchmarks for *Giardia lamblia* and viruses as described in § 141.709. Prior to changing the disinfection practice, the system must notify the State and must include in this notice the information in paragraphs (a)(1) through (3) of this section.

(1) A completed disinfection profile and disinfection benchmark for *Giardia lamblia* and viruses as described in § 141.709.

(2) A description of the proposed change in disinfection practice.

(3) An analysis of how the proposed change will affect the current level of disinfection.

(b) Significant changes to disinfection practice are defined as follows:

(1) Changes to the point of disinfection;

(2) Changes to the disinfectant(s) used in the treatment plant;

(3) Changes to the disinfection process; or

(4) Any other modification identified by the State as a significant change to disinfection practice.

§ 141.709 Developing the disinfection profile and benchmark.

(a) Systems required to develop disinfection profiles under § 141.708 must follow the requirements of this section. Systems must monitor at least weekly for a period of 12 consecutive months to determine the total log inactivation for *Giardia lamblia* and viruses. If systems monitor more frequently, the monitoring frequency must be evenly spaced. Systems that operate for fewer than 12 months per year must monitor weekly during the period of operation. Systems must determine log inactivation for *Giardia lamblia* through the entire plant, based on $CT_{99.9}$ values in Tables 1.1 through 1.6, 2.1 and 3.1 of § 141.74(b) as applicable. Systems must determine log inactivation for viruses through the entire treatment plant based on a protocol approved by the State.

(b) Systems with a single point of disinfectant application prior to the entrance to the distribution system must conduct the monitoring in paragraphs (b)(1) through (4) of this section. Systems with more than one point of disinfectant application must conduct the monitoring in paragraphs (b)(1) through (4) of this section for each disinfection segment. Systems must monitor the parameters necessary to determine the total inactivation ratio, using analytical methods in § 141.74(a).

(1) For systems using a disinfectant other than UV, the temperature of the disinfected water must be measured at each residual disinfectant concentration sampling point during peak hourly flow or at an alternative location approved by the State.

(2) For systems using chlorine, the pH of the disinfected water must be measured at each chlorine residual disinfectant concentration sampling point during peak hourly flow or at an alternative location approved by the State.

(3) The disinfectant contact time(s) (t) must be determined during peak hourly flow.

(4) The residual disinfectant concentration(s) (C) of the water before or at the first customer and prior to each additional point of disinfectant application must be measured during peak hourly flow.

(c) In lieu of conducting new monitoring under paragraph (b) of this section, systems may elect to meet the requirements of paragraphs (c)(1) or (2) of this section.

(1) Systems that have at least one year of existing data that are substantially equivalent to data collected under the provisions of paragraph (b) of this section may use these data to develop disinfection profiles as specified in this section if the system has neither made a significant change to its treatment practice nor changed sources since the data were collected. Systems may develop disinfection profiles using up to three years of existing data.

(2) Systems may use disinfection profile(s) developed under § 141.172 or §§ 141.530 through 141.536 in lieu of developing a new profile if the system has neither made a significant change to its treatment practice nor changed sources since the profile was developed. Systems that have not developed a virus profile under § 141.172 or §§ 141.530 through 141.536 must develop a virus profile using the same monitoring data on which the *Giardia lamblia* profile is based.

(d) Systems must calculate the total inactivation ratio for *Giardia lamblia* as specified in paragraphs (d)(1) through (3) of this section.

(1) Systems using only one point of disinfectant application may determine the total inactivation ratio for the disinfection segment based on either of the methods in paragraph (d)(1)(i) or (ii) of this section.

(i) Determine one inactivation ratio ($CTcalc/CT_{99.9}$) before or at the first customer during peak hourly flow.

(ii) Determine successive $CTcalc/CT_{99.9}$ values, representing sequential inactivation ratios, between the point of disinfectant application and a point before or at the first customer during peak hourly flow. The system must

calculate the total inactivation ratio by determining ($CTcalc/CT_{99.9}$) for each sequence and then adding the ($CTcalc/CT_{99.9}$) values together to determine ($\Sigma(CTcalc/CT_{99.9})$).

(2) Systems using more than one point of disinfectant application before the first customer must determine the CT value of each disinfection segment immediately prior to the next point of disinfectant application, or for the final segment, before or at the first customer, during peak hourly flow. The ($CTcalc/CT_{99.9}$) value of each segment and ($\Sigma(CTcalc/CT_{99.9})$) must be calculated using the method in paragraph (d)(1)(ii) of this section.

(3) The system must determine the total logs of inactivation by multiplying the value calculated in paragraph (d)(1) or (d)(2) of this section by 3.0.

(4) Systems must calculate the log of inactivation for viruses using a protocol approved by the State.

(e) Systems must use the procedures specified in paragraphs (e)(1) and (2) of this section to calculate a disinfection benchmark.

(1) For each year of profiling data collected and calculated under paragraphs (a) through (d) of this section, systems must determine the lowest mean monthly level of both *Giardia lamblia* and virus inactivation. Systems must determine the mean *Giardia lamblia* and virus inactivation for each calendar month for each year of profiling data by dividing the sum of daily or weekly *Giardia lamblia* and virus log inactivation by the number of values calculated for that month.

(2) The disinfection benchmark is the lowest monthly mean value (for systems with one year of profiling data) or the mean of the lowest monthly mean values (for systems with more than one year of profiling data) of *Giardia lamblia* and virus log inactivation in each year of profiling data.

Treatment Technique Requirements

§ 141.710 Bin classification for filtered systems.

(a) Following completion of the initial round of source water monitoring required under § 141.701(a), filtered systems must calculate an initial *Cryptosporidium* bin concentration for each plant for which monitoring was required. Calculation of the bin concentration must use the *Cryptosporidium* results reported under § 141.701(a) and must follow the procedures in paragraphs (b)(1) through (5) of this section.

(b)(1) For systems that collect a total of at least 48 samples, the bin concentration is equal to the arithmetic mean of all sample concentrations.

(2) For systems that collect a total of at least 24 samples, but not more than 47 samples, the bin concentration is equal to the highest arithmetic mean of all sample concentrations in any 12 consecutive months during which *Cryptosporidium* samples were collected.

(3) For systems that serve fewer than 10,000 people and monitor for *Cryptosporidium* for only one year (i.e., collect 24 samples in 12 months), the bin concentration is equal to the arithmetic mean of all sample concentrations.

(4) For systems with plants operating only part of the year that monitor fewer than 12 months per year under § 141.701(e), the bin concentration is equal to the highest arithmetic mean of all sample concentrations during any year of *Cryptosporidium* monitoring.

(5) If the monthly *Cryptosporidium* sampling frequency varies, systems must first calculate a monthly average for each month of monitoring. Systems must then use these monthly average concentrations, rather than individual sample concentrations, in the applicable calculation for bin classification in paragraphs (b)(1) through (4) of this section.

(c) Filtered systems must determine their initial bin classification from the following table and using the *Cryptosporidium* bin concentration calculated under paragraphs (a)–(b) of this section:

BIN CLASSIFICATION TABLE FOR FILTERED SYSTEMS

For systems that are:	With a *Cryptosporidium* bin concentration of . . .[1]	The bin classification is . . .
. . . required to monitor for *Cryptosporidium* under § 141.701.	*Cryptosporidium* <0.075 oocyst/L	Bin 1.
	0.075 oocysts/L ≤*Cryptosporidium* <1.0 oocysts/L	Bin 2.
	1.0 oocysts/L ≤*Cryptosporidium* <3.0 oocysts/L	Bin 3.
	Cryptosporidium ≥3.0 oocysts/L	Bin 4.
. . . serving fewer than 10,000 people and NOT required to monitor for *Cryptosporidium* under § 141.701(a)(4).	NA	Bin 1.

[1] Based on calculations in paragraph (a) or (d) of this section, as applicable.

(d) Following completion of the second round of source water monitoring required under § 141.701(b), filtered systems must recalculate their *Cryptosporidium* bin concentration using the *Cryptosporidium* results reported under § 141.701(b) and following the procedures in paragraphs (b)(1) through (4) of this section. Systems must then redetermine their bin classification using this bin concentration and the table in paragraph (c) of this section.

(e)(1) Filtered systems must report their initial bin classification under paragraph (c) of this section to the State for approval no later than 6 months after the system is required to complete initial source water monitoring based on the schedule in § 141.701(c).

(2) Systems must report their bin classification under paragraph (d) of this section to the State for approval no later than 6 months after the system is required to complete the second round of source water monitoring based on the schedule in § 141.701(c).

(3) The bin classification report to the State must include a summary of source water monitoring data and the calculation procedure used to determine bin classification.

(f) Failure to comply with the conditions of paragraph (e) of this section is a violation of the treatment technique requirement.

§ 141.711 Filtered system additional *Cryptosporidium* treatment requirements.

(a) Filtered systems must provide the level of additional treatment for *Cryptosporidium* specified in this paragraph based on their bin classification as determined under § 141.710 and according to the schedule in § 141.713.

If the system bin classification is . . .	And the system uses the following filtration treatment in full compliance with subparts H, P, and T of this part (as applicable), then the additional *Cryptosporidium* treatment requirements are . . .			
	Conventional filtration treatment (including softening)	Direct filtration	Slow sand or diatomaceous earth filtration	Alternative filtration technologies
Bin 1	No additional treatment	No additional treatment	No additional treatment	No additional treatment.
Bin 2	1-log treatment	1.5-log treatment	1-log treatment	[1]
Bin 3	2-log treatment	2.5-log treatment	2-log treatment	[2]
Bin 4	2.5-log treatment	3-log treatment	2.5-log treatment	[3]

[1] As determined by the State such that the total *Cryptosporidium* removal and inactivation is at least 4.0-log.
[2] As determined by the State such that the total *Cryptosporidium* removal and inactivation is at least 5.0-log.
[3] As determined by the State such that the total *Cryptosporidium* removal and inactivation is at least 5.5-log.

(b)(1) Filtered systems must use one or more of the treatment and management options listed in § 141.715, termed the microbial toolbox, to comply with the additional *Cryptosporidium* treatment required in paragraph (a) of this section.

(2) Systems classified in Bin 3 and Bin 4 must achieve at least 1-log of the additional *Cryptosporidium* treatment required under paragraph (a) of this section using either one or a combination of the following: bag filters, bank filtration, cartridge filters, chlorine dioxide, membranes, ozone, or UV, as described in §§ 141.716 through 141.720.

(c) Failure by a system in any month to achieve treatment credit by meeting criteria in §§ 141.716 through 141.720 for microbial toolbox options that is at least equal to the level of treatment required in paragraph (a) of this section is a violation of the treatment technique requirement.

(d) If the State determines during a sanitary survey or an equivalent source water assessment that after a system completed the monitoring conducted under § 141.701(a) or § 141.701(b), significant changes occurred in the system's watershed that could lead to increased contamination of the source water by *Cryptosporidium,* the system must take actions specified by the State to address the contamination. These actions may include additional source water monitoring and/or implementing microbial toolbox options listed in § 141.715.

§ 141.712 Unfiltered system *Cryptosporidium* treatment requirements.

(a) *Determination of mean Cryptosporidium level.* (1) Following completion of the initial source water monitoring required under § 141.701(a), unfiltered systems must calculate the arithmetic mean of all *Cryptosporidium* sample concentrations reported under § 141.701(a). Systems must report this value to the State for approval no later than 6 months after the month the system is required to complete initial source water monitoring based on the schedule in § 141.701(c).

(2) Following completion of the second round of source water monitoring required under § 141.701(b), unfiltered systems must calculate the arithmetic mean of all *Cryptosporidium* sample concentrations reported under § 141.701(b). Systems must report this value to the State for approval no later than 6 months after the month the system is required to complete the second round of source water monitoring based on the schedule in § 141.701(c).

(3) If the monthly *Cryptosporidium* sampling frequency varies, systems must first calculate a monthly average for each month of monitoring. Systems must then use these monthly average concentrations, rather than individual sample concentrations, in the calculation of the mean *Cryptosporidium* level in paragraphs (a)(1) or (2) of this section.

(4) The report to the State of the mean *Cryptosporidium* levels calculated under paragraphs (a)(1) and (2) of this section must include a summary of the source water monitoring data used for the calculation.

(5) Failure to comply with the conditions of paragraph (a) of this section is a violation of the treatment technique requirement.

(b) *Cryptosporidium inactivation requirements.* Unfiltered systems must provide the level of inactivation for *Cryptosporidium* specified in this paragraph, based on their mean *Cryptosporidium* levels as determined under paragraph (a) of this section and according to the schedule in § 141.713.

(1) Unfiltered systems with a mean *Cryptosporidium* level of 0.01 oocysts/L or less must provide at least 2-log *Cryptosporidium* inactivation.

(2) Unfiltered systems with a mean *Cryptosporidium* level of greater than 0.01 oocysts/L must provide at least 3-log *Cryptosporidium* inactivation.

(c) *Inactivation treatment technology requirements.* Unfiltered systems must use chlorine dioxide, ozone, or UV as described in § 141.720 to meet the *Cryptosporidium* inactivation requirements of this section.

(1) Systems that use chlorine dioxide or ozone and fail to achieve the *Cryptosporidium* inactivation required in paragraph (b) of this section on more than one day in the calendar month are in violation of the treatment technique requirement.

(2) Systems that use UV light and fail to achieve the *Cryptosporidium* inactivation required in paragraph (b) of this section by meeting the criteria in § 141.720(d)(3)(ii) are in violation of the treatment technique requirement.

(d) *Use of two disinfectants.* Unfiltered systems must meet the combined *Cryptosporidium* inactivation requirements of this section and *Giardia lamblia* and virus inactivation requirements of § 141.72(a) using a minimum of two disinfectants, and each of two disinfectants must separately achieve the total inactivation required for either *Cryptosporidium, Giardia lamblia,* or viruses.

§ 141.713 Schedule for compliance with *Cryptosporidium* treatment requirements.

(a) Following initial bin classification under § 141.710(c), filtered systems must provide the level of treatment for *Cryptosporidium* required under § 141.711 according to the schedule in paragraph (c) of this section.

(b) Following initial determination of the mean *Cryptosporidium* level under § 141.712(a)(1), unfiltered systems must provide the level of treatment for *Cryptosporidium* required under § 141.712 according to the schedule in paragraph (c) of this section.

(c) *Cryptosporidium treatment compliance dates.*

CRYPTOSPORIDIUM TREATMENT COMPLIANCE DATES TABLE

Systems that serve . . .	Must comply with Cryptosporidium treatment requirements no later than . . .[a]
(1) At least 100,000 people.	(i) April 1, 2012.
(2) From 50,000 to 99,999 people.	(i) October 1, 2012.
(3) From 10,000 to 49,999 people.	(i) October 1, 2013.
(4) Fewer than 10,000 people.	(i) October 1, 2014.

[a] States may allow up to an additional two years for complying with the treatment requirement for systems making capital improvements.

(d) If the bin classification for a filtered system changes following the second round of source water monitoring, as determined under § 141.710(d), the system must provide the level of treatment for *Cryptosporidium* required under § 141.711 on a schedule the State approves.

(e) If the mean *Cryptosporidium* level for an unfiltered system changes following the second round of monitoring, as determined under § 141.712(a)(2), and if the system must provide a different level of *Cryptosporidium* treatment under § 141.712 due to this change, the system must meet this treatment requirement on a schedule the State approves.

§ 141.714 Requirements for uncovered finished water storage facilities.

(a) Systems using uncovered finished water storage facilities must comply with the conditions of this section.

(b) Systems must notify the State of the use of each uncovered finished water storage facility no later than April 1, 2008.

(c) Systems must meet the conditions of paragraph (c)(1) or (2) of this section for each uncovered finished water storage facility or be in compliance with a State-approved schedule to meet these conditions no later than April 1, 2009.

(1) Systems must cover any uncovered finished water storage facility.

(2) Systems must treat the discharge from the uncovered finished water storage facility to the distribution system to achieve inactivation and/or removal of at least 4-log virus, 3-log *Giardia lamblia,* and 2-log *Cryptosporidium* using a protocol approved by the State.

(d) Failure to comply with the requirements of this section is a violation of the treatment technique requirement.

Requirements for Microbial Toolbox Components

§ 141.715 Microbial toolbox options for meeting *Cryptosporidium* treatment requirements.

(a)(1) Systems receive the treatment credits listed in the table in paragraph (b) of this section by meeting the conditions for microbial toolbox options described in §§ 141.716 through 141.720. Systems apply these treatment credits to meet the treatment requirements in § 141.711 or § 141.712, as applicable.

(2) Unfiltered systems are eligible for treatment credits for the microbial toolbox options described in § 141.720 only.

(b) The following table summarizes options in the microbial toolbox:

MICROBIAL TOOLBOX SUMMARY TABLE: OPTIONS, TREATMENT CREDITS AND CRITERIA

Toolbox Option	*Cryptosporidium* treatment credit with design and implementation criteria
Source Protection and Management Toolbox Options	
(1) Watershed control program	0.5-log credit for State-approved program comprising required elements, annual program status report to State, and regular watershed survey. Unfiltered systems are not eligible for credit. Specific criteria are in § 141.716(a).
(2) Alternative source/intake management	No prescribed credit. Systems may conduct simultaneous monitoring for treatment bin classification at alternative intake locations or under alternative intake management strategies. Specific criteria are in § 141.716(b).
Pre Filtration Toolbox Options	
(3) Presedimentation basin with coagulation	0.5-log credit during any month that presedimentation basins achieve a monthly mean reduction of 0.5-log or greater in turbidity or alternative State-approved performance criteria. To be eligible, basins must be operated continuously with coagulant addition and all plant flow must pass through basins. Specific criteria are in § 141.717(a).
(4) Two-stage lime softening	0.5-log credit for two-stage softening where chemical addition and hardness precipitation occur in both stages. All plant flow must pass through both stages. Single-stage softening is credited as equivalent to conventional treatment. Specific criteria are in § 141.717(b).
(5) Bank filtration	0.5-log credit for 25-foot setback; 1.0-log credit for 50-foot setback; aquifer must be unconsolidated sand containing at least 10 percent fines; average turbidity in wells must be less than 1 NTU. Systems using wells followed by filtration when conducting source water monitoring must sample the well to determine bin classification and are not eligible for additional credit. Specific criteria are in § 141.717(c).
Treatment Performance Toolbox Options	
(6) Combined filter performance	0.5-log credit for combined filter effluent turbidity less than or equal to 0.15 NTU in at least 95 percent of measurements each month. Specific criteria are in § 141.718(a).
(7) Individual filter performance	0.5-log credit (in addition to 0.5-log combined filter performance credit) if individual filter effluent turbidity is less than or equal to 0.15 NTU in at least 95 percent of samples each month in each filter and is never greater than 0.3 NTU in two consecutive measurements in any filter. Specific criteria are in § 141.718(b).
(8) Demonstration of performance	Credit awarded to unit process or treatment train based on a demonstration to the State with a State- approved protocol. Specific criteria are in § 141.718(c).

MICROBIAL TOOLBOX SUMMARY TABLE: OPTIONS, TREATMENT CREDITS AND CRITERIA—Continued

Toolbox Option	*Cryptosporidium* treatment credit with design and implementation criteria
Additional Filtration Toolbox Options	
(9) Bag or cartridge filters (individual filters)	Up to 2-log credit based on the removal efficiency demonstrated during challenge testing with a 1.0-log factor of safety. Specific criteria are in § 141.719(a).
(10) Bag or cartridge filters (in series)	Up to 2.5-log credit based on the removal efficiency demonstrated during challenge testing with a 0.5-log factor of safety. Specific criteria are in § 141.719(a).
(11) Membrane filtration	Log credit equivalent to removal efficiency demonstrated in challenge test for device if supported by direct integrity testing. Specific criteria are in § 141.719(b).
(12) Second stage filtration	0.5-log credit for second separate granular media filtration stage if treatment train includes coagulation prior to first filter. Specific criteria are in § 141.719(c)
(13) Slow sand filters	2.5-log credit as a secondary filtration step; 3.0-log credit as a primary filtration process. No prior chlorination for either option. Specific criteria are in § 141.719(d).
Inactivation Toolbox Options	
(14) Chlorine dioxide	Log credit based on measured CT in relation to CT table. Specific criteria in § 141.720(b)
(15) Ozone	Log credit based on measured CT in relation to CT table. Specific criteria in § 141.720(b).
(16) UV	Log credit based on validated UV dose in relation to UV dose table; reactor validation testing required to establish UV dose and associated operating conditions. Specific criteria in § 141.720(d).

§ 141.716 Source toolbox components.

(a) *Watershed control program.* Systems receive 0.5-log *Cryptosporidium* treatment credit for implementing a watershed control program that meets the requirements of this section.

(1) Systems that intend to apply for the watershed control program credit must notify the State of this intent no later than two years prior to the treatment compliance date applicable to the system in § 141.713.

(2) Systems must submit to the State a proposed watershed control plan no later than one year before the applicable treatment compliance date in § 141.713. The State must approve the watershed control plan for the system to receive watershed control program treatment credit. The watershed control plan must include the elements in paragraphs (a)(2)(i) through (iv) of this section.

(i) Identification of an ''area of influence'' outside of which the likelihood of *Cryptosporidium* or fecal contamination affecting the treatment plant intake is not significant. This is the area to be evaluated in future watershed surveys under paragraph (a)(5)(ii) of this section.

(ii) Identification of both potential and actual sources of *Cryptosporidium* contamination and an assessment of the relative impact of these sources on the system's source water quality.

(iii) An analysis of the effectiveness and feasibility of control measures that could reduce *Cryptosporidium* loading from sources of contamination to the system's source water.

(iv) A statement of goals and specific actions the system will undertake to reduce source water *Cryptosporidium* levels. The plan must explain how the actions are expected to contribute to specific goals, identify watershed partners and their roles, identify resource requirements and commitments, and include a schedule for plan implementation with deadlines for completing specific actions identified in the plan.

(3) Systems with existing watershed control programs (*i.e.,* programs in place on January 5, 2006) are eligible to seek this credit. Their watershed control plans must meet the criteria in paragraph (a)(2) of this section and must specify ongoing and future actions that will reduce source water *Cryptosporidium* levels.

(4) If the State does not respond to a system regarding approval of a watershed control plan submitted under this section and the system meets the other requirements of this section, the watershed control program will be considered approved and 0.5 log *Cryptosporidium* treatment credit will be awarded unless and until the State subsequently withdraws such approval.

(5) Systems must complete the actions in paragraphs (a)(5)(i) through (iii) of this section to maintain the 0.5-log credit.

(i) Submit an annual watershed control program status report to the State. The annual watershed control program status report must describe the system's implementation of the approved plan and assess the adequacy of the plan to meet its goals. It must explain how the system is addressing any shortcomings in plan implementation, including those previously identified by the State or as the result of the watershed survey conducted under paragraph (a)(5)(ii) of this section. It must also describe any significant changes that have occurred in the watershed since the last watershed sanitary survey. If a system determines during implementation that making a significant change to its approved watershed control program is necessary, the system must notify the State prior to making any such changes. If any change is likely to reduce the level of source water protection, the system must also list in its notification the actions the system will take to mitigate this effect.

(ii) Undergo a watershed sanitary survey every three years for community water systems and every five years for noncommunity water systems and submit the survey report to the State. The survey must be conducted according to State guidelines and by persons the State approves.

(A) The watershed sanitary survey must meet the following criteria: encompass the region identified in the State-approved watershed control plan as the area of influence; assess the implementation of actions to reduce source water *Cryptosporidium* levels; and identify any significant new sources of *Cryptosporidium.*

(B) If the State determines that significant changes may have occurred in the watershed since the previous watershed sanitary survey, systems must undergo another watershed sanitary survey by a date the State requires, which may be earlier than the regular date in paragraph (a)(5)(ii) of this section.

(iii) The system must make the watershed control plan, annual status reports, and watershed sanitary survey reports available to the public upon

request. These documents must be in a plain language style and include criteria by which to evaluate the success of the program in achieving plan goals. The State may approve systems to withhold from the public portions of the annual status report, watershed control plan, and watershed sanitary survey based on water supply security considerations.

(6) If the State determines that a system is not carrying out the approved watershed control plan, the State may withdraw the watershed control program treatment credit.

(b) *Alternative source.* (1) A system may conduct source water monitoring that reflects a different intake location (either in the same source or for an alternate source) or a different procedure for the timing or level of withdrawal from the source (alternative source monitoring). If the State approves, a system may determine its bin classification under § 141.710 based on the alternative source monitoring results.

(2) If systems conduct alternative source monitoring under paragraph (b)(1) of this section, systems must also monitor their current plant intake concurrently as described in § 141.701.

(3) Alternative source monitoring under paragraph (b)(1) of this section must meet the requirements for source monitoring to determine bin classification, as described in §§ 141.701 through 141.706. Systems must report the alternative source monitoring results to the State, along with supporting information documenting the operating conditions under which the samples were collected.

(4) If a system determines its bin classification under § 141.710 using alternative source monitoring results that reflect a different intake location or a different procedure for managing the timing or level of withdrawal from the source, the system must relocate the intake or permanently adopt the withdrawal procedure, as applicable, no later than the applicable treatment compliance date in § 141.713.

§ 141.717 Pre-filtration treatment toolbox components.

(a) *Presedimentation.* Systems receive 0.5-log *Cryptosporidium* treatment credit for a presedimentation basin during any month the process meets the criteria in this paragraph.

(1) The presedimentation basin must be in continuous operation and must treat the entire plant flow taken from a surface water or GWUDI source.

(2) The system must continuously add a coagulant to the presedimentation basin.

(3) The presedimentation basin must achieve the performance criteria in paragraph (3)(i) or (ii) of this section.

(i) Demonstrates at least 0.5-log mean reduction of influent turbidity. This reduction must be determined using daily turbidity measurements in the presedimentation process influent and effluent and must be calculated as follows: $\log_{10}$(monthly mean of daily influent turbidity) − $\log_{10}$(monthly mean of daily effluent turbidity).

(ii) Complies with State-approved performance criteria that demonstrate at least 0.5-log mean removal of micron-sized particulate material through the presedimentation process.

(b) *Two-stage lime softening.* Systems receive an additional 0.5-log *Cryptosporidium* treatment credit for a two-stage lime softening plant if chemical addition and hardness precipitation occur in two separate and sequential softening stages prior to filtration. Both softening stages must treat the entire plant flow taken from a surface water or GWUDI source.

(c) *Bank filtration.* Systems receive *Cryptosporidium* treatment credit for bank filtration that serves as pretreatment to a filtration plant by meeting the criteria in this paragraph. Systems using bank filtration when they begin source water monitoring under § 141.701(a) must collect samples as described in § 141.703(d) and are not eligible for this credit.

(1) Wells with a ground water flow path of at least 25 feet receive 0.5-log treatment credit; wells with a ground water flow path of at least 50 feet receive 1.0-log treatment credit. The ground water flow path must be determined as specified in paragraph (c)(4) of this section.

(2) Only wells in granular aquifers are eligible for treatment credit. Granular aquifers are those comprised of sand, clay, silt, rock fragments, pebbles or larger particles, and minor cement. A system must characterize the aquifer at the well site to determine aquifer properties. Systems must extract a core from the aquifer and demonstrate that in at least 90 percent of the core length, grains less than 1.0 mm in diameter constitute at least 10 percent of the core material.

(3) Only horizontal and vertical wells are eligible for treatment credit.

(4) For vertical wells, the ground water flow path is the measured distance from the edge of the surface water body under high flow conditions (determined by the 100 year floodplain elevation boundary or by the floodway, as defined in Federal Emergency Management Agency flood hazard maps) to the well screen. For horizontal wells, the ground water flow path is the measured distance from the bed of the river under normal flow conditions to the closest horizontal well lateral screen.

(5) Systems must monitor each wellhead for turbidity at least once every four hours while the bank filtration process is in operation. If monthly average turbidity levels, based on daily maximum values in the well, exceed 1 NTU, the system must report this result to the State and conduct an assessment within 30 days to determine the cause of the high turbidity levels in the well. If the State determines that microbial removal has been compromised, the State may revoke treatment credit until the system implements corrective actions approved by the State to remediate the problem.

(6) Springs and infiltration galleries are not eligible for treatment credit under this section, but are eligible for credit under § 141.718(c).

(7) *Bank filtration demonstration of performance.* The State may approve *Cryptosporidium* treatment credit for bank filtration based on a demonstration of performance study that meets the criteria in this paragraph. This treatment credit may be greater than 1.0-log and may be awarded to bank filtration that does not meet the criteria in paragraphs (c)(1)–(5) of this section.

(i) The study must follow a State-approved protocol and must involve the collection of data on the removal of *Cryptosporidium* or a surrogate for *Cryptosporidium* and related hydrogeologic and water quality parameters during the full range of operating conditions.

(ii) The study must include sampling both from the production well(s) and from monitoring wells that are screened and located along the shortest flow path between the surface water source and the production well(s).

§ 141.718 Treatment performance toolbox components.

(a) *Combined filter performance.* Systems using conventional filtration treatment or direct filtration treatment receive an additional 0.5-log *Cryptosporidium* treatment credit during any month the system meets the criteria in this paragraph. Combined filter effluent (CFE) turbidity must be less than or equal to 0.15 NTU in at least 95 percent of the measurements. Turbidity must be measured as described in § 141.74(a) and (c).

(b) *Individual filter performance.* Systems using conventional filtration treatment or direct filtration treatment receive 0.5-log *Cryptosporidium* treatment credit, which can be in

addition to the 0.5-log credit under paragraph (a) of this section, during any month the system meets the criteria in this paragraph. Compliance with these criteria must be based on individual filter turbidity monitoring as described in § 141.174 or § 141.560, as applicable.

(1) The filtered water turbidity for each individual filter must be less than or equal to 0.15 NTU in at least 95 percent of the measurements recorded each month.

(2) No individual filter may have a measured turbidity greater than 0.3 NTU in two consecutive measurements taken 15 minutes apart.

(3) Any system that has received treatment credit for individual filter performance and fails to meet the requirements of paragraph (b)(1) or (2) of this section during any month does not receive a treatment technique violation under § 141.711(c) if the State determines the following:

(i) The failure was due to unusual and short-term circumstances that could not reasonably be prevented through optimizing treatment plant design, operation, and maintenance.

(ii) The system has experienced no more than two such failures in any calendar year.

(c) *Demonstration of performance.* The State may approve *Cryptosporidium* treatment credit for drinking water treatment processes based on a demonstration of performance study that meets the criteria in this paragraph. This treatment credit may be greater than or less than the prescribed treatment credits in § 141.711 or §§ 141.717 through 141.720 and may be awarded to treatment processes that do not meet the criteria for the prescribed credits.

(1) Systems cannot receive the prescribed treatment credit for any toolbox box option in §§ 141.717 through 141.720 if that toolbox option is included in a demonstration of performance study for which treatment credit is awarded under this paragraph.

(2) The demonstration of performance study must follow a State-approved protocol and must demonstrate the level of *Cryptosporidium* reduction the treatment process will achieve under the full range of expected operating conditions for the system.

(3) Approval by the State must be in writing and may include monitoring and treatment performance criteria that the system must demonstrate and report on an ongoing basis to remain eligible for the treatment credit. The State may designate such criteria where necessary to verify that the conditions under which the demonstration of performance credit was approved are maintained during routine operation.

§ 141.719 Additional filtration toolbox components.

(a) *Bag and cartridge filters.* Systems receive *Cryptosporidium* treatment credit of up to 2.0-log for individual bag or cartridge filters and up to 2.5-log for bag or cartridge filters operated in series by meeting the criteria in paragraphs (a)(1) through (10) of this section. To be eligible for this credit, systems must report the results of challenge testing that meets the requirements of paragraphs (a)(2) through (9) of this section to the State. The filters must treat the entire plant flow taken from a subpart H source.

(1) The *Cryptosporidium* treatment credit awarded to bag or cartridge filters must be based on the removal efficiency demonstrated during challenge testing that is conducted according to the criteria in paragraphs (a)(2) through (a)(9) of this section. A factor of safety equal to 1-log for individual bag or cartridge filters and 0.5-log for bag or cartridge filters in series must be applied to challenge testing results to determine removal credit. Systems may use results from challenge testing conducted prior to January 5, 2006 if the prior testing was consistent with the criteria specified in paragraphs (a)(2) through (9) of this section.

(2) Challenge testing must be performed on full-scale bag or cartridge filters, and the associated filter housing or pressure vessel, that are identical in material and construction to the filters and housings the system will use for removal of *Cryptosporidium.* Bag or cartridge filters must be challenge tested in the same configuration that the system will use, either as individual filters or as a series configuration of filters.

(3) Challenge testing must be conducted using *Cryptosporidium* or a surrogate that is removed no more efficiently than *Cryptosporidium.* The microorganism or surrogate used during challenge testing is referred to as the challenge particulate. The concentration of the challenge particulate must be determined using a method capable of discreetly quantifying the specific microorganism or surrogate used in the test; gross measurements such as turbidity may not be used.

(4) The maximum feed water concentration that can be used during a challenge test must be based on the detection limit of the challenge particulate in the filtrate (i.e., filtrate detection limit) and must be calculated using the following equation:

$$\text{Maximum Feed Concentration} = 1 \times 10^{4} \times (\text{Filtrate Detection Limit})$$

(5) Challenge testing must be conducted at the maximum design flow rate for the filter as specified by the manufacturer.

(6) Each filter evaluated must be tested for a duration sufficient to reach 100 percent of the terminal pressure drop, which establishes the maximum pressure drop under which the filter may be used to comply with the requirements of this subpart.

(7) Removal efficiency of a filter must be determined from the results of the challenge test and expressed in terms of log removal values using the following equation:

$$LRV = LOG_{10}(C_f) - LOG_{10}(C_p)$$

Where:

LRV = log removal value demonstrated during challenge testing; C_f = the feed concentration measured during the challenge test; and C_p = the filtrate concentration measured during the challenge test. In applying this equation, the same units must be used for the feed and filtrate concentrations. If the challenge particulate is not detected in the filtrate, then the term C_p must be set equal to the detection limit.

(8) Each filter tested must be challenged with the challenge particulate during three periods over the filtration cycle: within two hours of start-up of a new filter; when the pressure drop is between 45 and 55 percent of the terminal pressure drop; and at the end of the cycle after the pressure drop has reached 100 percent of the terminal pressure drop. An LRV must be calculated for each of these challenge periods for each filter tested. The LRV for the filter (LRV_{filter}) must be assigned the value of the minimum LRV observed during the three challenge periods for that filter.

(9) If fewer than 20 filters are tested, the overall removal efficiency for the filter product line must be set equal to the lowest LRV_{filter} among the filters tested. If 20 or more filters are tested, the overall removal efficiency for the filter product line must be set equal to the 10th percentile of the set of LRV_{filter} values for the various filters tested. The percentile is defined by (i/(n+1)) where i is the rank of n individual data points ordered lowest to highest. If necessary, the 10th percentile may be calculated using linear interpolation.

(10) If a previously tested filter is modified in a manner that could change the removal efficiency of the filter product line, challenge testing to demonstrate the removal efficiency of

the modified filter must be conducted and submitted to the State.

(b) *Membrane filtration.* (1) Systems receive *Cryptosporidium* treatment credit for membrane filtration that meets the criteria of this paragraph. Membrane cartridge filters that meet the definition of membrane filtration in § 141.2 are eligible for this credit. The level of treatment credit a system receives is equal to the lower of the values determined under paragraph (b)(1)(i) and (ii) of this section.

(i) The removal efficiency demonstrated during challenge testing conducted under the conditions in paragraph (b)(2) of this section.

(ii) The maximum removal efficiency that can be verified through direct integrity testing used with the membrane filtration process under the conditions in paragraph (b)(3) of this section.

(2) *Challenge Testing.* The membrane used by the system must undergo challenge testing to evaluate removal efficiency, and the system must report the results of challenge testing to the State. Challenge testing must be conducted according to the criteria in paragraphs (b)(2)(i) through (vii) of this section. Systems may use data from challenge testing conducted prior to January 5, 2006 if the prior testing was consistent with the criteria in paragraphs (b)(2)(i) through (vii) of this section.

(i) Challenge testing must be conducted on either a full-scale membrane module, identical in material and construction to the membrane modules used in the system's treatment facility, or a smaller-scale membrane module, identical in material and similar in construction to the full-scale module. A module is defined as the smallest component of a membrane unit in which a specific membrane surface area is housed in a device with a filtrate outlet structure.

(ii) Challenge testing must be conducted using *Cryptosporidium* oocysts or a surrogate that is removed no more efficiently than *Cryptosporidium* oocysts. The organism or surrogate used during challenge testing is referred to as the challenge particulate. The concentration of the challenge particulate, in both the feed and filtrate water, must be determined using a method capable of discretely quantifying the specific challenge particulate used in the test; gross measurements such as turbidity may not be used.

(iii) The maximum feed water concentration that can be used during a challenge test is based on the detection limit of the challenge particulate in the filtrate and must be determined according to the following equation:

$$\text{Maximum Feed Concentration} = 3.16 \times 10^6 \times (\text{Filtrate Detection Limit})$$

(iv) Challenge testing must be conducted under representative hydraulic conditions at the maximum design flux and maximum design process recovery specified by the manufacturer for the membrane module. Flux is defined as the throughput of a pressure driven membrane process expressed as flow per unit of membrane area. Recovery is defined as the volumetric percent of feed water that is converted to filtrate over the course of an operating cycle uninterrupted by events such as chemical cleaning or a solids removal process (*i.e.*, backwashing).

(v) Removal efficiency of a membrane module must be calculated from the challenge test results and expressed as a log removal value according to the following equation:

$$LRV = LOG_{10}(C_f) \times LOG_{10}(C_p)$$

Where:

LRV = log removal value demonstrated during the challenge test; C_f = the feed concentration measured during the challenge test; and C_p = the filtrate concentration measured during the challenge test. Equivalent units must be used for the feed and filtrate concentrations. If the challenge particulate is not detected in the filtrate, the term C_p is set equal to the detection limit for the purpose of calculating the LRV. An LRV must be calculated for each membrane module evaluated during the challenge test.

(vi) The removal efficiency of a membrane filtration process demonstrated during challenge testing must be expressed as a log removal value ($LRV_{C\text{-}Test}$). If fewer than 20 modules are tested, then $LRV_{C\text{-}Test}$ is equal to the lowest of the representative LRVs among the modules tested. If 20 or more modules are tested, then $LRV_{C\text{-}Test}$ is equal to the 10th percentile of the representative LRVs among the modules tested. The percentile is defined by (i/(n+1)) where i is the rank of n individual data points ordered lowest to highest. If necessary, the 10th percentile may be calculated using linear interpolation.

(vii) The challenge test must establish a quality control release value (QCRV) for a non-destructive performance test that demonstrates the *Cryptosporidium* removal capability of the membrane filtration module. This performance test must be applied to each production membrane module used by the system that was not directly challenge tested in order to verify *Cryptosporidium* removal capability. Production modules that do not meet the established QCRV are not eligible for the treatment credit demonstrated during the challenge test.

(viii) If a previously tested membrane is modified in a manner that could change the removal efficiency of the membrane or the applicability of the non-destructive performance test and associated QCRV, additional challenge testing to demonstrate the removal efficiency of, and determine a new QCRV for, the modified membrane must be conducted and submitted to the State.

(3) *Direct integrity testing.* Systems must conduct direct integrity testing in a manner that demonstrates a removal efficiency equal to or greater than the removal credit awarded to the membrane filtration process and meets the requirements described in paragraphs (b)(3)(i) through (vi) of this section. A direct integrity test is defined as a physical test applied to a membrane unit in order to identify and isolate integrity breaches (*i.e.*, one or more leaks that could result in contamination of the filtrate).

(i) The direct integrity test must be independently applied to each membrane unit in service. A membrane unit is defined as a group of membrane modules that share common valving that allows the unit to be isolated from the rest of the system for the purpose of integrity testing or other maintenance.

(ii) The direct integrity method must have a resolution of 3 micrometers or less, where resolution is defined as the size of the smallest integrity breach that contributes to a response from the direct integrity test.

(iii) The direct integrity test must have a sensitivity sufficient to verify the log treatment credit awarded to the membrane filtration process by the State, where sensitivity is defined as the maximum log removal value that can be reliably verified by a direct integrity test. Sensitivity must be determined using the approach in either paragraph (b)(3)(iii)(A) or (B) of this section as applicable to the type of direct integrity test the system uses.

(A) For direct integrity tests that use an applied pressure or vacuum, the direct integrity test sensitivity must be calculated according to the following equation:

$$LRV_{DIT} = LOG_{10}\,(Q_p / (VCF \times Q_{breach}))$$

Where:

LRV_{DIT} = the sensitivity of the direct integrity test; Q_p = total design filtrate flow from the membrane unit; Q_{breach} = flow of water from an

integrity breach associated with the smallest integrity test response that can be reliably measured, and VCF = volumetric concentration factor. The volumetric concentration factor is the ratio of the suspended solids concentration on the high pressure side of the membrane relative to that in the feed water.

(B) For direct integrity tests that use a particulate or molecular marker, the direct integrity test sensitivity must be calculated according to the following equation:

$$LRV_{DIT} = LOG_{10}(C_f) - LOG_{10}(C_p)$$

Where:

LRV_{DIT} = the sensitivity of the direct integrity test; C_f = the typical feed concentration of the marker used in the test; and C_p = the filtrate concentration of the marker from an integral membrane unit.

(iv) Systems must establish a control limit within the sensitivity limits of the direct integrity test that is indicative of an integral membrane unit capable of meeting the removal credit awarded by the State.

(v) If the result of a direct integrity test exceeds the control limit established under paragraph (b)(3)(iv) of this section, the system must remove the membrane unit from service. Systems must conduct a direct integrity test to verify any repairs, and may return the membrane unit to service only if the direct integrity test is within the established control limit.

(vi) Systems must conduct direct integrity testing on each membrane unit at a frequency of not less than once each day that the membrane unit is in operation. The State may approve less frequent testing, based on demonstrated process reliability, the use of multiple barriers effective for *Cryptosporidium*, or reliable process safeguards.

(4) *Indirect integrity monitoring.* Systems must conduct continuous indirect integrity monitoring on each membrane unit according to the criteria in paragraphs (b)(4)(i) through (v) of this section. Indirect integrity monitoring is defined as monitoring some aspect of filtrate water quality that is indicative of the removal of particulate matter. A system that implements continuous direct integrity testing of membrane units in accordance with the criteria in paragraphs (b)(3)(i) through (v) of this section is not subject to the requirements for continuous indirect integrity monitoring. Systems must submit a monthly report to the State summarizing all continuous indirect integrity monitoring results triggering direct integrity testing and the corrective action that was taken in each case.

(i) Unless the State approves an alternative parameter, continuous indirect integrity monitoring must include continuous filtrate turbidity monitoring.

(ii) Continuous monitoring must be conducted at a frequency of no less than once every 15 minutes.

(iii) Continuous monitoring must be separately conducted on each membrane unit.

(iv) If indirect integrity monitoring includes turbidity and if the filtrate turbidity readings are above 0.15 NTU for a period greater than 15 minutes (i.e., two consecutive 15-minute readings above 0.15 NTU), direct integrity testing must immediately be performed on the associated membrane unit as specified in paragraphs (b)(3)(i) through (v) of this section.

(v) If indirect integrity monitoring includes a State-approved alternative parameter and if the alternative parameter exceeds a State-approved control limit for a period greater than 15 minutes, direct integrity testing must immediately be performed on the associated membrane units as specified in paragraphs (b)(3)(i) through (v) of this section.

(c) *Second stage filtration.* Systems receive 0.5-log *Cryptosporidium* treatment credit for a separate second stage of filtration that consists of sand, dual media, GAC, or other fine grain media following granular media filtration if the State approves. To be eligible for this credit, the first stage of filtration must be preceded by a coagulation step and both filtration stages must treat the entire plant flow taken from a surface water or GWUDI source. A cap, such as GAC, on a single stage of filtration is not eligible for this credit. The State must approve the treatment credit based on an assessment of the design characteristics of the filtration process.

(d) *Slow sand filtration (as secondary filter).* Systems are eligible to receive 2.5-log *Cryptosporidium* treatment credit for a slow sand filtration process that follows a separate stage of filtration if both filtration stages treat entire plant flow taken from a surface water or GWUDI source and no disinfectant residual is present in the influent water to the slow sand filtration process. The State must approve the treatment credit based on an assessment of the design characteristics of the filtration process. This paragraph does not apply to treatment credit awarded to slow sand filtration used as a primary filtration process.

§ 141.720 Inactivation toolbox components.

(a) *Calculation of CT values.* (1) CT is the product of the disinfectant contact time (T, in minutes) and disinfectant concentration (C, in milligrams per liter). Systems with treatment credit for chlorine dioxide or ozone under paragraph (b) or (c) of this section must calculate CT at least once each day, with both C and T measured during peak hourly flow as specified in §§ 141.74(a) through (b).

(2) Systems with several disinfection segments in sequence may calculate CT for each segment, where a disinfection segment is defined as a treatment unit process with a measurable disinfectant residual level and a liquid volume. Under this approach, systems must add the *Cryptosporidium* CT values in each segment to determine the total CT for the treatment plant.

(b) *CT values for chlorine dioxide and ozone.* (1) Systems receive the *Cryptosporidium* treatment credit listed in this table by meeting the corresponding chlorine dioxide CT value for the applicable water temperature, as described in paragraph (a) of this section.

CT VALUES (MG·MIN/L) FOR *Cryptosporidium* INACTIVATION BY CHLORINE DIOXIDE [1]

Log credit	Water Temperature, °C										
	<=0.5	1	2	3	5	7	10	15	20	25	30
(i) 0.25	159	153	140	128	107	90	69	45	29	19	12
(ii) 0.5	319	305	279	256	214	180	138	89	58	38	24
(iii) 1.0	637	610	558	511	429	360	277	179	116	75	49
(iv) 1.5	956	915	838	767	643	539	415	268	174	113	73
(v) 2.0	1275	1220	1117	1023	858	719	553	357	232	150	98
(vi) 2.5	1594	1525	1396	1278	1072	899	691	447	289	188	122

CT VALUES (MG·MIN/L) FOR *Cryptosporidium* INACTIVATION BY CHLORINE DIOXIDE [1]—Continued

Log credit	Water Temperature, °C										
	<=0.5	1	2	3	5	7	10	15	20	25	30
(vii) 3.0	1912	1830	1675	1534	1286	1079	830	536	347	226	147

[1] Systems may use this equation to determine log credit between the indicated values: Log credit = $(0.001506 \times (1.09116)^{Temp}) \times CT$.

(2) Systems receive the *Cryptosporidium* treatment credit listed in this table by meeting the corresponding ozone CT values for the applicable water temperature, as described in paragraph (a) of this section.

CT VALUES (MG·MIN/L) FOR *Cryptosporidium* INACTIVATION BY OZONE [1]

Log credit	Water Temperature, °C										
	<=0.5	1	2	3	5	7	10	15	20	25	30
(i) 0.25	6.0	5.8	5.2	4.8	4.0	3.3	2.5	1.6	1.0	0.6	0.39
(ii) 0.5	12	12	10	9.5	7.9	6.5	4.9	3.1	2.0	1.2	0.78
(iii) 1.0	24	23	21	19	16	13	9.9	6.2	3.9	2.5	1.6
(iv) 1.5	36	35	31	29	24	20	15	9.3	5.9	3.7	2.4
(v) 2.0	48	46	42	38	32	26	20	12	7.8	4.9	3.1
(vi) 2.5	60	58	52	48	40	33	25	16	9.8	6.2	3.9
(vii) 3.0	72	69	63	57	47	39	30	19	12	7.4	4.7

[1] Systems may use this equation to determine log credit between the indicated values: Log credit = $(0.0397 \times (1.09757)^{Temp}) \times CT$.

(c) *Site-specific study.* The State may approve alternative chlorine dioxide or ozone CT values to those listed in paragraph (b) of this section on a site-specific basis. The State must base this approval on a site-specific study a system conducts that follows a State-approved protocol.

(d) *Ultraviolet light.* Systems receive *Cryptosporidium, Giardia lamblia,* and virus treatment credits for ultraviolet (UV) light reactors by achieving the corresponding UV dose values shown in paragraph (d)(1) of this section. Systems must validate and monitor UV reactors as described in paragraphs (d)(2) and (3) of this section to demonstrate that they are achieving a particular UV dose value for treatment credit.

(1) *UV dose table.* The treatment credits listed in this table are for UV light at a wavelength of 254 nm as produced by a low pressure mercury vapor lamp. To receive treatment credit for other lamp types, systems must demonstrate an equivalent germicidal dose through reactor validation testing, as described in paragraph (d)(2) of this section. The UV dose values in this table are applicable only to post-filter applications of UV in filtered systems and to unfiltered systems.

UV DOSE TABLE FOR *Cryptosporidium, Giardia lamblia,* AND VIRUS INACTIVATION CREDIT

Log credit	*Cryptosporidium* UV dose (mJ/cm^2)	*Giardia lamblia* UV dose (mJ/cm^2)	Virus UV dose (mJ/cm^2)
(i) 0.5	1.6	1.5	39
(ii) 1.0	2.5	2.1	58
(iii) 1.5	3.9	3.0	79
(iv) 2.0	5.8	5.2	100
(v) 2.5	8.5	7.7	121
(vi) 3.0	12	11	143
(vii) 3.5	15	15	163
(viii) 4.0	22	22	186

(2) *Reactor validation testing.* Systems must use UV reactors that have undergone validation testing to determine the operating conditions under which the reactor delivers the UV dose required in paragraph (d)(1) of this section (*i.e.,* validated operating conditions). These operating conditions must include flow rate, UV intensity as measured by a UV sensor, and UV lamp status.

(i) When determining validated operating conditions, systems must account for the following factors: UV absorbance of the water; lamp fouling and aging; measurement uncertainty of on-line sensors; UV dose distributions arising from the velocity profiles through the reactor; failure of UV lamps or other critical system components; and inlet and outlet piping or channel configurations of the UV reactor.

(ii) Validation testing must include the following: Full scale testing of a reactor that conforms uniformly to the UV reactors used by the system and inactivation of a test microorganism whose dose response characteristics have been quantified with a low pressure mercury vapor lamp.

(iii) The State may approve an alternative approach to validation testing.

(3) *Reactor monitoring.* (i) Systems must monitor their UV reactors to determine if the reactors are operating within validated conditions, as determined under paragraph (d)(2) of this section. This monitoring must include UV intensity as measured by a UV sensor, flow rate, lamp status, and other parameters the State designates

based on UV reactor operation. Systems must verify the calibration of UV sensors and must recalibrate sensors in accordance with a protocol the State approves.

(ii) To receive treatment credit for UV light, systems must treat at least 95 percent of the water delivered to the public during each month by UV reactors operating within validated conditions for the required UV dose, as described in paragraphs (d)(1) and (2) of this section. Systems must demonstrate compliance with this condition by the monitoring required under paragraph (d)(3)(i) of this section.

Reporting and Recordkeeping Requirements

§ 141.721 Reporting requirements.

(a) Systems must report sampling schedules under § 141.702 and source water monitoring results under § 141.706 unless they notify the State that they will not conduct source water monitoring due to meeting the criteria of § 141.701(d).

(b) Systems must report the use of uncovered finished water storage facilities to the State as described in § 141.714.

(c) Filtered systems must report their *Cryptosporidium* bin classification as described in § 141.710.

(d) Unfiltered systems must report their mean source water *Cryptosporidium* level as described in § 141.712.

(e) Systems must report disinfection profiles and benchmarks to the State as described in §§ 141.708 through 141.709 prior to making a significant change in disinfection practice.

(f) Systems must report to the State in accordance with the following table for any microbial toolbox options used to comply with treatment requirements under § 141.711 or § 141.712. Alternatively, the State may approve a system to certify operation within required parameters for treatment credit rather than reporting monthly operational data for toolbox options.

MICROBIAL TOOLBOX REPORTING REQUIREMENTS

Toolbox option	Systems must submit the following information	On the following schedule
(1) Watershed control program (WCP).	(i) Notice of intention to develop a new or continue an existing watershed control program.	No later than two years before the applicable treatment compliance date in § 141.713
	(ii) Watershed control plan	No later than one year before the applicable treatment compliance date in § 141.713.
	(iii) Annual watershed control program status report	Every 12 months, beginning one year after the applicable treatment compliance date in § 141.713.
	(iv) Watershed sanitary survey report	For community water systems, every three years beginning three years after the applicable treatment compliance date in § 141.713. For noncommunity water systems, every five years beginning five years after the applicable treatment compliance date in § 141.713.
(2) Alternative source/intake management.	Verification that system has relocated the intake or adopted the intake withdrawal procedure reflected in monitoring results.	No later than the applicable treatment compliance date in § 141.713.
(3) Presedimentation	Monthly verification of the following: (i) Continuous basin operation (ii) Treatment of 100% of the flow (iii) Continuous addition of a coagulant (iv) At least 0.5-log mean reduction of influent turbidity or compliance with alternative State-approved performance criteria.	Monthly reporting within 10 days following the month in which the monitoring was conducted, beginning on the applicable treatment compliance date in § 141.713.
(4) Two-stage lime softening	Monthly verification of the following: (i) Chemical addition and hardness precipitation occurred in two separate and sequential softening stages prior to filtration (ii) Both stages treated 100% of the plant flow.	Monthly reporting within 10 days following the month in which the monitoring was conducted, beginning on the applicable treatment compliance date in § 141.713.
(5) Bank filtration	(i) Initial demonstration of the following: (A) Unconsolidated, predominantly sandy aquifer (B) Setback distance of at least 25 ft. (0.5-log credit) or 50 ft. (1.0-log credit).	No later than the applicable treatment compliance date in § 141.713.
	(ii) If monthly average of daily max turbidity is greater than 1 NTU then system must report result and submit an assessment of the cause..	Report within 30 days following the month in which the monitoring was conducted, beginning on the applicable treatment compliance date in § 141.713.
(6) Combined filter performance.	Monthly verification of combined filter effluent (CFE) turbidity levels less than or equal to 0.15 NTU in at least 95 percent of the 4 hour CFE measurements taken each month.	Monthly reporting within 10 days following the month in which the monitoring was conducted, beginning on the applicable treatment compliance date in § 141.713.
(7) Individual filter performance.	Monthly verification of the following: (i) Individual filter effluent (IFE) turbidity levels less than or equal to 0.15 NTU in at least 95 percent of samples each month in each filter (ii) No individual filter greater than 0.3 NTU in two consecutive readings 15 minutes apart.	Monthly reporting within 10 days following the month in which the monitoring was conducted, beginning on the applicable treatment compliance date in § 141.713.]
(8) Demonstration of performance.	(i) Results from testing following a State approved protocol.	No later than the applicable treatment compliance date in § 141.713.
	(ii) As required by the State, monthly verification of operation within conditions of State approval for demonstration of performance credit.	Within 10 days following the month in which monitoring was conducted, beginning on the applicable treatment compliance date in § 141.713.

MICROBIAL TOOLBOX REPORTING REQUIREMENTS—Continued

Toolbox option	Systems must submit the following information	On the following schedule
(9) Bag filters and cartridge filters.	(i) Demonstration that the following criteria are met: (A) Process meets the definition of bag or cartridge filtration; (B) Removal efficiency established through challenge testing that meets criteria in this subpart.	No later than the applicable treatment compliance date in § 141.713.
	(ii) Monthly verification that 100% of plant flow was filtered.	Within 10 days following the month in which monitoring was conducted, beginning on the applicable treatment compliance date in § 141.713.
(10) Membrane filtration	(i) Results of verification testing demonstrating the following: (A) Removal efficiency established through challenge testing that meets criteria in this subpart; (B) Integrity test method and parameters, including resolution, sensitivity, test frequency, control limits, and associated baseline.	No later than the applicable treatment compliance date in § 141.713.
	(ii) Monthly report summarizing the following: (A) All direct integrity tests above the control limit; (B) If applicable, any turbidity or alternative state-approved indirect integrity monitoring results triggering direct integrity testing and the corrective action that was taken.	Within 10 days following the month in which monitoring was conducted, beginning on the applicable treatment compliance date in § 141.713.
(11) Second stage filtration ..	Monthly verification that 100% of flow was filtered through both stages and that first stage was preceded by coagulation step.	Within 10 days following the month in which monitoring was conducted, beginning on the applicable treatment compliance date in § 141.713.
(12) Slow sand filtration (as secondary filter).	Monthly verification that both a slow sand filter and a preceding separate stage of filtration treated 100% of flow from subpart H sources..	Within 10 days following the month in which monitoring was conducted, beginning on the applicable treatment compliance date in § 141.713.
(13) Chlorine dioxide	Summary of CT values for each day as described in § 141.720..	Within 10 days following the month in which monitoring was conducted, beginning on the applicable treatment compliance date in § 141.713.
(14) Ozone	Summary of CT values for each day as described in § 141.720..	Within 10 days following the month in which monitoring was conducted, beginning on the applicable treatment compliance date in § 141.713.
(15) UV	(i) Validation test results demonstrating operating conditions that achieve required UV dose.	No later than the applicable treatment compliance date in § 141.713.
	(ii) Monthly report summarizing the percentage of water entering the distribution system that was not treated by UV reactors operating within validated conditions for the required dose as specified in 141.720(d)..	Within 10 days following the month in which monitoring was conducted, beginning on the applicable treatment compliance date in § 141.713.

§ 141.722 Recordkeeping requirements.

(a) Systems must keep results from the initial round of source water monitoring under § 141.701(a) and the second round of source water monitoring under § 141.701(b) until 3 years after bin classification under § 141.710 for filtered systems or determination of the mean *Cryptosporidium* level under § 141.710 for unfiltered systems for the particular round of monitoring.

(b) Systems must keep any notification to the State that they will not conduct source water monitoring due to meeting the criteria of § 141.701(d) for 3 years.

(c) Systems must keep the results of treatment monitoring associated with microbial toolbox options under §§ 141.716 through 141.720 and with uncovered finished water reservoirs under § 141.714, as applicable, for 3 years.

Requirements for Sanitary Surveys Performed by EPA

§ 141.723 Requirements to respond to significant deficiencies identified in sanitary surveys performed by EPA.

(a) A sanitary survey is an onsite review of the water source (identifying sources of contamination by using results of source water assessments where available), facilities, equipment, operation, maintenance, and monitoring compliance of a PWS to evaluate the adequacy of the PWS, its sources and operations, and the distribution of safe drinking water.

(b) For the purposes of this section, a significant deficiency includes a defect in design, operation, or maintenance, or a failure or malfunction of the sources, treatment, storage, or distribution system that EPA determines to be causing, or has the potential for causing the introduction of contamination into the water delivered to consumers.

(c) For sanitary surveys performed by EPA, systems must respond in writing to significant deficiencies identified in sanitary survey reports no later than 45 days after receipt of the report, indicating how and on what schedule the system will address significant deficiencies noted in the survey.

(d) Systems must correct significant deficiencies identified in sanitary survey reports according to the schedule approved by EPA, or if there is no approved schedule, according to the schedule reported under paragraph (c) of this section if such deficiencies are within the control of the system.

PART 142—NATIONAL PRIMARY DRINKING WATER REGULATIONS IMPLEMENTATION

■ 8. The authority citation for part 142 continues to read as follows:

Authority: 42 U.S.C. 300f, 300g-1, 300g-2, 300g-3, 300g-4, 300g-5, 300g-6, 300j-4, 300j-9 and 300j-11.

■ 9. Section 142.14 is amended by adding paragraph (a)(9) to read as follows:

§ 142.14 Records kept by States.

* * * * *

(a) * * *

(9) Any decisions made pursuant to the provisions of part 141, subpart W of this chapter.

(i) Results of source water *E. coli* and *Cryptosporidium* monitoring.

(ii) The bin classification after the initial and after the second round of source water monitoring for each filtered system, as described in § 141.710 of this chapter.

(iii) Any change in treatment requirements for filtered systems due to watershed assessment during sanitary surveys, as described in § 141.711(d) of this chapter.

(iv) The determination of whether the mean *Cryptosporidium* level is greater than 0.01 oocysts/L after the initial and after the second round of source water monitoring for each unfiltered system, as described in § 141.712(a) of this chapter.

(v) The treatment processes or control measures that systems use to meet their *Cryptosporidium* treatment requirements under § 141.711 or § 141.712 of this chapter.

(vi) A list of systems required to cover or treat the effluent of an uncovered finished water storage facility, as specified in § 141.714 of this chapter.

* * * * *

■ 10. Section 142.15 is amended by adding paragraph (c)(6) to read as follows:

§ 142.15 Reports by States.

(c) * * *

(6) *Subpart W.* (i) The bin classification after the initial and after the second round of source water monitoring for each filtered system, as described in § 141.710 of this chapter.

(ii) Any change in treatment requirements for these systems due to watershed assessment during sanitary surveys, as described in § 141.711(d) of this chapter.

(iii) The determination of whether the mean *Cryptosporidium* level is greater than 0.01 oocysts/L both after the initial and after the second round of source water monitoring for each unfiltered system, as described in § 141.712(a) of this chapter.

* * * * *

■ 11. Section 142.16 is amended by adding paragraph (n) to read as follows:

§ 142.16 Special primacy conditions.

* * * * *

(n) *Requirements for States to adopt 40 CFR part 141, subpart W.* In addition to the general primacy requirements elsewhere in this part, including the requirements that State regulations be at least as stringent as Federal requirements, an application for approval of a State program revision that adopts 40 CFR part 141, subpart W, must contain a description of how the State will accomplish the following program requirements where allowed in State programs.

(1) Approve an alternative to the *E. coli* levels that trigger *Cryptosporidium* monitoring by filtered systems serving fewer than 10,000 people, as described in § 141.701(a)(5).

(2) Assess significant changes in the watershed and source water as part of the sanitary survey process and determine appropriate follow-up action for systems, as described in § 141.711(d) of this chapter.

(3) Approve watershed control programs for the 0.5-log treatment credit in the microbial toolbox, as described in § 141.716(a) of this chapter.

(4) Approve protocols for demonstration of performance treatment credits in the microbial toolbox, as allowed under § 141.718(c) of this chapter.

(5) Approve protocols for alternative ozone and chlorine dioxide CT values in the microbial toolbox, as allowed under § 141.720(c) of this chapter.

(6) Approve an alternative approach to UV reactor validation testing in the microbial toolbox, as allowed under § 141.720(d)(2)(iii) of this chapter.

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